

## Severe dialyzer dysfunction undetectable by standard reprocessing validation tests

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**Severe dialyzer dysfunction undetectable by standard reprocessing validation tests.** It is generally accepted that careful monitoring of total cell volume and ultrafiltration rates will ensure adequate function of reprocessed dialyzers. During routine urea kinetic measurements we noted that the percent of patients with clearances less than 200 ml/min increased from 5% to 48% despite adherence to these validation tests. As these patients did not have evidence of recirculation in the vascular access, possible causes of dialyzer dysfunction were investigated. Injection of methylene blue into the dialysate port revealed non-uniform flow of dialysate in dialyzers from patients with markedly reduced clearances. In vitro studies of dialyzers subjected to sequential daily reprocessing, without patient exposure, demonstrated that in vitro clearances declined in one lot but not another. The initial clearances of  $218 \pm 4$  ml/min fell progressively to  $112 \pm 18$  ( $P < 0.001$ ) after 15 reuses. No effects of reprocessing were found in a different lot ( $230 \pm 2$  vs.  $226 \pm 4$  ml/min). Soaking the dialyzers from the affected lot in either the disinfectant or dialysate solution caused a decline in the clearances which was less than that of serial reuse. Although the magnitude of the problem of dialyzer malfunction with reuse is unknown, careful attention to dialyzer function is warranted in patients treated with reprocessed dialyzers.

Since Shaldon, Silva and Rosen [1] first described reuse of dialyzers in 1964, there has been increasing and widespread acceptance of the procedure. It is estimated that 70% of patients in the United States are currently treated with dialyzers undergoing some form of reprocessing [2]. During routine urea kinetic studies, we recently noted an alarming decline in the clearances of patients treated with reprocessed dialyzers. This occurred without alterations in standard validation tests used to judge dialyzer function. We, therefore, attempted to define the problem and identify possible causes to account for the observation.

### Methods

The Chromalloy American Kidney Center is a 28 station, 160 patient, free-standing dialysis unit owned and operated by Washington University School of Medicine. High-efficiency dialysis was performed on 97% of patients using Fresenius

A2008 C or A2008 D machines (Seratronics, Concord, California, USA). Maximum blood flow rates ranged from 400 to 430 ml/min and dialysate flow rates from 500 to 800 ml/min. Urea kinetics were performed routinely every two months and the dialysis prescription was altered as necessary to maintain a KT/V of greater than 1.0 [3]. The mean duration of dialysis was 2.6 hours (range 2 to 4 hours). Sixty-eight percent of patients were dialyzed with Clirans TAF 12 (Terumo Corp., Japan) and 19 percent with Clirans TAF 10 dialyzers. All but one patient were treated with dialyzers which were reprocessed with DRS 4 Dialyzer Reprocessing System (Seratronics). The details of the system are described elsewhere [4]. In brief, this was a multi-station, automated reprocessing system which employed several rinses with reverse ultrafiltration transmembrane pressures as high as 1200 mm Hg (fiber intraluminal pressure negative). Bleach (sodium hypochlorite), at a maximum concentration of 0.75%, and an exposure time of six minutes, was employed as a cleansing agent. Glutaraldehyde (0.8%) (Nephrex, Surgicos, Arlington, Texas) was used for disinfection and storage. All steps were performed according to manufacturers' recommendations. The reprocessing procedure began within 10 minutes of termination of dialysis in the vast majority of cases. Dialyzers were discarded if any of the following rejection criteria were met: 1) total cell volume (TCV) less than 80% of the initial TCV (TCV is sometimes also referred to as "fiber bundle volume"); 2) ultrafiltration rates (UFR) less than 75% of the initial UFR; 3) evidence of a pressure leakage; or 4) greater than 15 clotted fibers on visual inspection. The mean number of reuses with this system was 19 (range 1 to 50).

Chromalloy-St. Anthony's Dialysis Center is a small, six station dialysis unit managed by Washington University School of Medicine. Patients were dialyzed with Centry 2 Rx (Cobe Laboratories, Inc., Lakewood, Colorado, USA) machines and Clirans dialyzers provided by Chromalloy American Kidney Center. Dialyzers were reprocessed with a Renatron RS 8300 (Renal Systems, Minneapolis, Minnesota, USA) single-station reprocessing device. This system employed several rinse steps with maximal reverse ultrafiltration transmembrane pressures of 250 mm Hg. Validation tests of dialyzer function were the same as the Seratronics system except for the absence of KUF monitoring. Renalin (Renal Systems), a formulation of peracetic acid, was used for disinfection.

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### Clearance measurements

The in vivo urea clearances were derived from urea kinetic modeling as described in detail by Gotch and Sargent [3] according to the formula:

$$K = \frac{-V}{T} \left[ \ln \left( 1 - \frac{\Delta C}{C_0} \right) \right]$$

where V = volume of distribution of urea (ml), T = time (minutes),  $\Delta C$  = absolute decline in BUN with dialysis (mg/dl), and  $C_0$  = predialysis BUN (mg/dl). Pre- and post-dialysis BUN levels were obtained twice during the same week for calculation of the clearances which were not corrected for access recirculation. The results were averaged in each patient. Total body water was estimated from the calculated surface area of each patient [5].

The in vitro low molecular weight clearances of the dialyzers were estimated using conductivity measurement technique [6,7]. This simple method involves the perfusion of dialysate through the dialysate side of the dialyzer and water (treated with reverse osmosis and deionization) through the "blood" path. In this non-recirculating system, the dialysate flow rate ( $Q_D$ ) averaged 525 ml/min. The water flow rate ( $Q_B$ ) was set at 300 ml/min. Both were measured with graduated cylinders over five minutes prior to each testing. The results were used in the calculation of clearances. Conductivity readings (80 BC Western Meter, Mesa Medical, Wheatridge, Colorado, USA) were determined, after a suitable equilibrium period (usually 15 min) from the dialysate outflow ( $C_{DO}$ ), dialysate inflow ( $C_{DI}$ ) and venous ( $C_{BO}$ ) lines. The clearances assume zero ultrafiltration and are given by the formulae:

$$K_B = \frac{Q_B(C_{BO})}{C_{DI}}$$

$$K_D = \frac{Q_D(C_{DI} - C_{DO})}{C_{DI}}$$

where  $K_B$  equals clearance on the blood side and  $K_D$  equals clearance on the dialysate side. Mass balance, obtained by dividing  $K_B$  by  $K_D$  was  $1.071 \pm 0.005$ . The interassay coefficient of variation for  $K_B$  in unprocessed dialyzers was 3.14%. All in vitro clearances reported are derived from  $K_B$  and were performed in a blinded fashion.

### In vitro studies

The effect of reprocessing on dialyzer function in the absence of patient exposure was assessed. Dialyzers from a lot judged to be associated with low in vivo clearances (lot #1) were compared to a lot which was associated with the expected in vivo clearances (lot #2).

**Experiment 1.** Clearances were measured in unused, unprocessed dialyzers from both lots. All dialyzers then underwent daily reprocessing in a fashion identical to that described above. Clearances were obtained after 5, 10, and 15 reprocessing procedures.

**Experiment 2.** Clearances in lot #1 were measured after 0, 1, 3, and 5 reprocessing procedures.

**Experiment 3.** Clearances from unused dialyzers in lots 1 and 2 were measured. Clearances were then repeated following soaking the dialyzers in either glutaraldehyde or dialysate for five days.

**Table 1.** Biochemical determinants

	Creatinine	BUN	Potassium
	mg/dl		mEq/liter
Period A			
Unaffected group	11.8 ± 0.6	70.9 ± 2.9	4.50 ± 0.08
Affected group	12.4 ± 0.5	73.0 ± 3.1	4.76 ± 0.12
Period B			
Unaffected group	11.8 ± 0.5	71.6 ± 2.8	4.59 ± 0.09
Affected group	14.2 ± 0.6 <sup>a</sup>	86.1 ± 3.2 <sup>b</sup>	5.02 ± 0.14 <sup>c</sup>

<sup>a</sup>  $P < 0.001$ ; <sup>b</sup>  $P < 0.01$ ; <sup>c</sup>  $P < 0.05$  compared to Period A (paired *t*-test)

### Biochemical determinations

Routine chemistries were performed by routine laboratory methods adjusted for the Technicon Auto Analyzer (Technicon Instruments Corporation, Tarrytown, New York, USA).

### Recirculation studies

In order to determine the adequacy of fistula flow rates, BUN levels were determined by simultaneously sampling blood from the arterial and venous ports of dialyzer tubing and from a contralateral vein. Recirculation studies were performed within 15 minutes following the initiation of dialysis. The percent recirculation is given by the formula:

$$\left( \frac{\text{peripheral BUN} - \text{arterial BUN}}{\text{peripheral BUN} - \text{venous BUN}} \right) \times 100$$

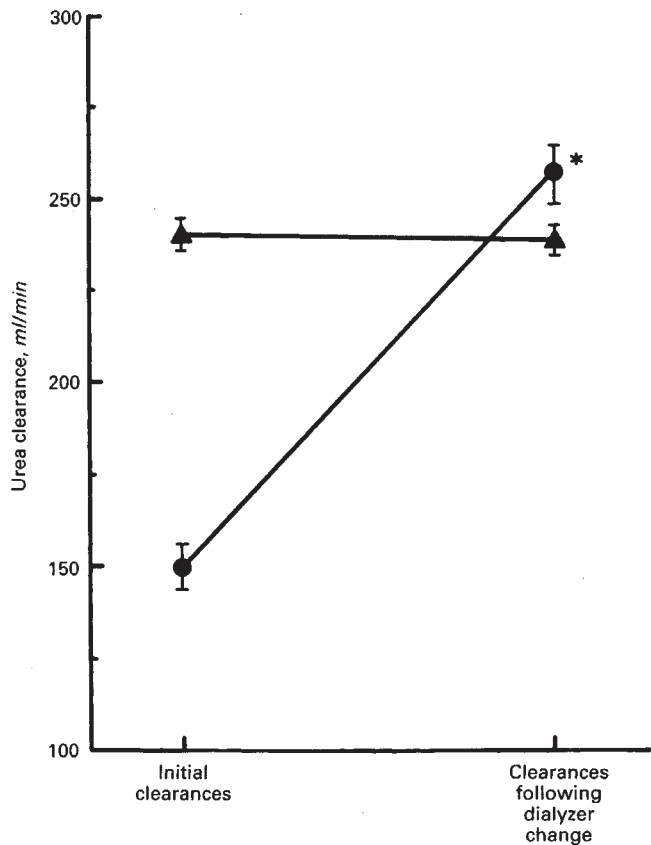
### Statistics

Statistical analysis was performed using the Student's *t*-test for paired or unpaired data and by correlation analysis. All results are reported as the mean ± SEM

### Results

During routine urea kinetic analysis, we noted that the percent of patients with urea clearances less than 200 ml/min was 48% (Period B). Review of kinetic analysis performed two months prior to this revealed that only 5% had urea clearances in this range (Period A). Three patients complained of nausea and increased somnolence. Recirculation studies on the affected subjects showed no evidence of reduced fistula function, as defined by less than 15% admixture. Routine pre-dialysis chemistries of the affected and unaffected groups during these two periods are summarized in Table 1. There were no significant changes in plasma creatinine, BUN, or potassium in the unaffected group. In the affected group, however, all biochemical determinations rose significantly from Period A to Period B.

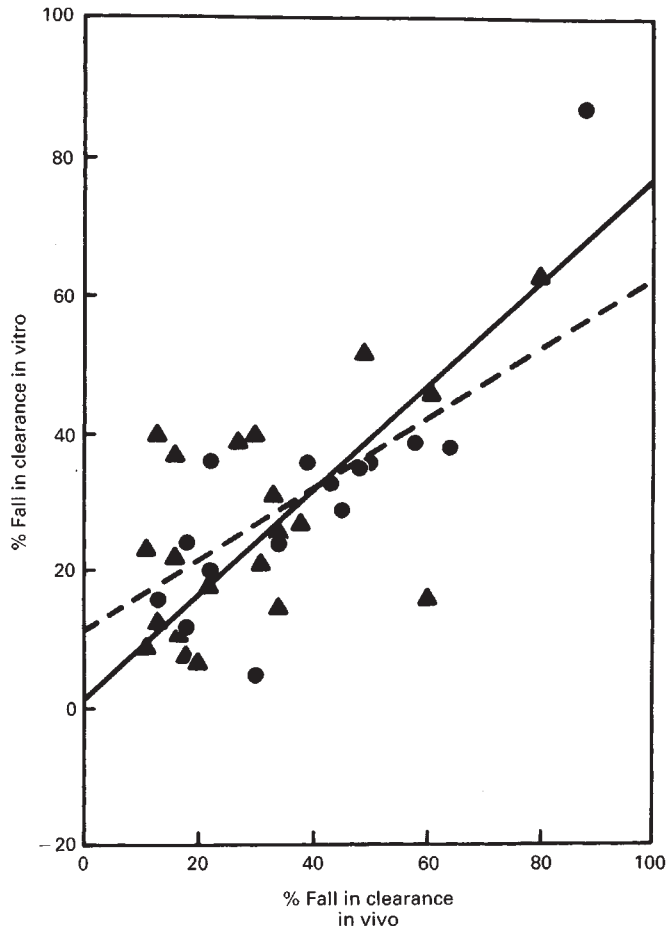
Because of the evidence of widespread dialyzer dysfunction, all patients were switched to new dialyzers and reprocessing was continued. Measurements of urea clearances were repeated within a week. In those 48 patients with urea clearances less than 200 ml/min, the clearance rose from  $150 \pm 5$  to  $256 \pm 6$  ml/min ( $P < 0.001$ ). In those 51 patients with clearances greater than 200 ml/min, there were no differences ( $241 \pm 5$  vs.  $240 \pm 4$  ml/min). Thus, the improvement in clearances in the former group did not represent a regression toward the mean. The data are summarized on Figure 1. There was no correlation between



**Fig. 1.** Urea clearances derived from urea kinetics in patients with clearances less than 200 ml/min (●) and in patients with clearances greater than 200 ml/min (▲). Repeat measurements performed following the change to new dialyzers revealed a marked improvement in clearances (\* $P < 0.001$ ) in those with low initial clearances whereas there was no difference in those with intact dialyzer function.

reuse number and urea kinetic-derived clearances in either group.

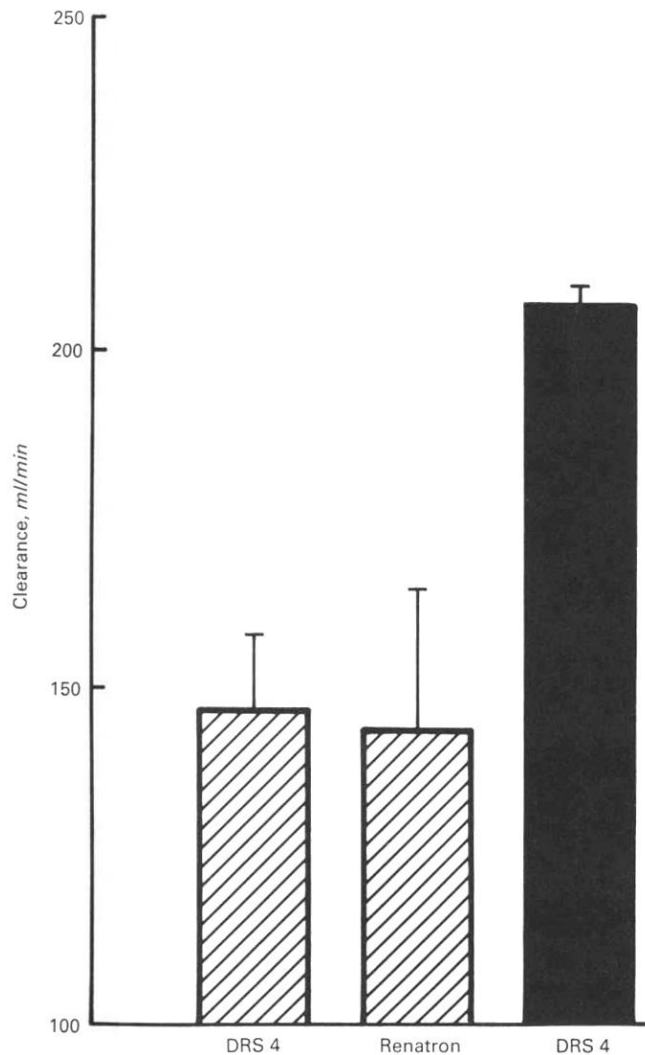
Two months following the change to different lots of TAF 12 and TAF 10 dialyzers and continued reprocessing, urea kinetics were remeasured in all patients. Impaired clearances in some patient were again noted. This was traced to one lot of TAF 12 dialyzers. All dialyzers in that lot were then studied in vitro using conductivity clearances. Twenty-five out of 37 dialyzers in the lot demonstrated reductions in clearances of greater than 10% of the manufacturer's specification. The mean clearances were  $161 \pm 8$  ml/min which compared to  $220 \pm 2$  ml/min in the 12 dialyzers with sustained function. The clearance of the entire lot was  $180 \pm 7$  ml/min. Urea kinetic-derived and in vitro clearances were compared in 21 of 25 of the dialyzers and a close correlation was seen (Fig. 2). There were no differences in the reuse number in those dialyzers with impaired and normal clearances ( $15 \pm 1$  vs.  $14 \pm 1$ , respectively). The in vitro clearances of a different lot of TAF 12 dialyzers reprocessed  $21 \pm 3$  times were all normal ( $223 \pm 2$  ml/min,  $N = 12$ ). These were significantly higher ( $P < 0.001$ ) than those clearances of the affected 25. Similarly, the in vitro clearances of a lot of TAF 10 dialyzers ( $N = 20$ ) were reduced to  $147 \pm 11$  ml/min following  $12 \pm 4$  reuses. This compared to clearances of  $207 \pm 3$  ml/min



**Fig. 2.** Correlation analysis of the relation between the % fall in predicted clearances determined in vitro using conductivity methodology and those derived from in vivo derived urea kinetics in a lot of dysfunctional TAF 12 dialyzers (▲,---) and TAF 10 dialyzers (●,—). A strong relationship was found for each lot ( $Y = 0.51 X + 12.2$ ,  $r = 0.610$ ,  $P < 0.01$  and  $Y = 0.76 X + 1.4$ ,  $r = 0.838$ ,  $P < 0.001$ , respectively).

in a separate lot of TAF 10 dialyzers ( $N = 11$ ,  $P < 0.001$ ) measured following  $21 \pm 5$  reuses. The reduction in in vitro clearances of the dysfunctional TAF 10 dialyzers also correlated with those found in vivo. This relationship is shown in Figure 2. The same lot of TAF 10 dialyzers was also utilized at our satellite unit that employs a different reprocessing procedure (Methods). The in vitro clearances of these seven dialyzers were  $144 \pm 21$  ml/min following  $13 \pm 1$  reprocessing treatments. These values were not different from those obtained with the same lot at Chromalloy American Kidney Center. Therefore the impaired function resulted from an intrinsic abnormality of the dialyzers and not from the type of reprocessing equipment utilized. These data are summarized in Figure 3.

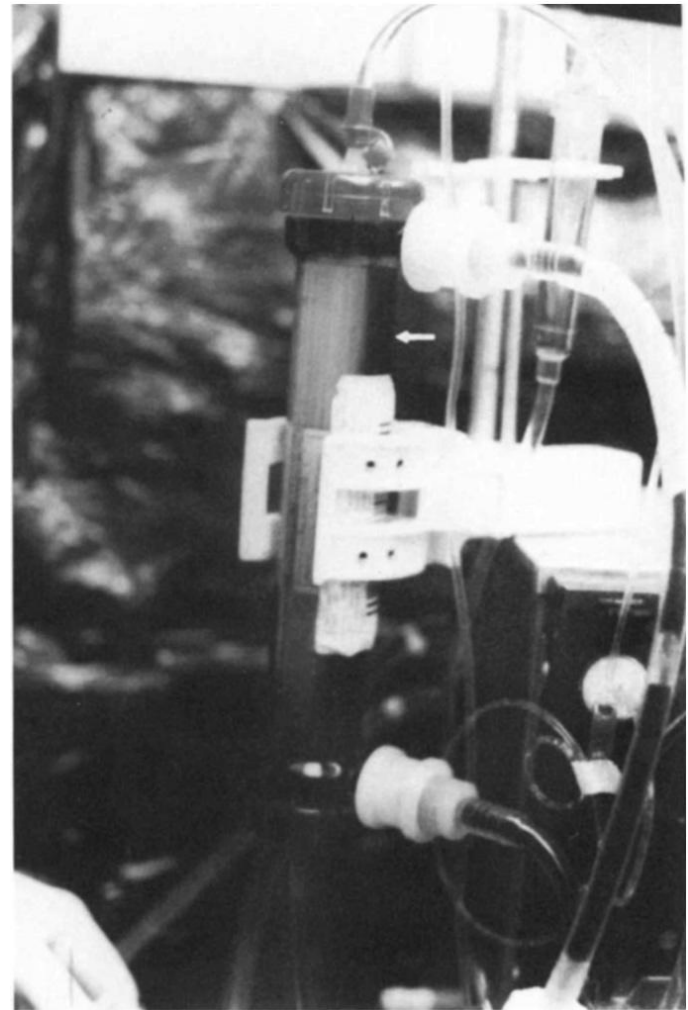
Because all dialyzers that demonstrated severe dysfunction passed the standard validation tests, we hypothesized that there was maldistribution of flow between the blood and dialysate paths. In order to test this possibility, dialyzers with severe dysfunction were tested on a Centry 2 dialysis machine in vitro by injecting methylene blue into the dialysate port. As can be seen from Figure 4, there was non-uniform flow of dialysate



**Fig. 3.** The effects of reprocessing systems and lot characteristics on conductivity clearance. Despite being treated by two distinctly different processes, dialyzers from a lot with low in vivo clearances (□), did not have different conductivity clearances. In contrast, dialyzers from a lot demonstrating normal in vivo function (■) showed higher in vitro clearances ( $P < 0.001$ ) despite undergoing reprocessing with one of the same systems (DRS 4).

along one side of the dialyzer (channeling). This was present in most, but not all, of the affected dialyzers. In comparison, the uniform flow of methylene blue in a non-affected dialyzer is shown in Figure 5.

In order to better define the mechanism of dialyzer dysfunction, further in vitro studies of seven TAF 12 dialyzers in a lot associated with poor clearances (lot #1) and seven dialyzers associated with intact clearances (lot #2) were performed. The clearances of the unused dialyzers in lot #1 and #2 were not different (Fig. 6). However, when retested after five daily reprocessing treatments (and storage in glutaraldehyde), the clearances of the dialyzers in lot #1 fell from  $217 \pm 4$  to  $128 \pm 11$  ml/min ( $P < 0.001$ ). After reprocessing 15 times, the clearances were  $111 \pm 18$  ml/min. No changes were noted in the dialyzers from lot #2 reprocessed 15 times ( $225 \pm 2$  vs.  $229 \pm$

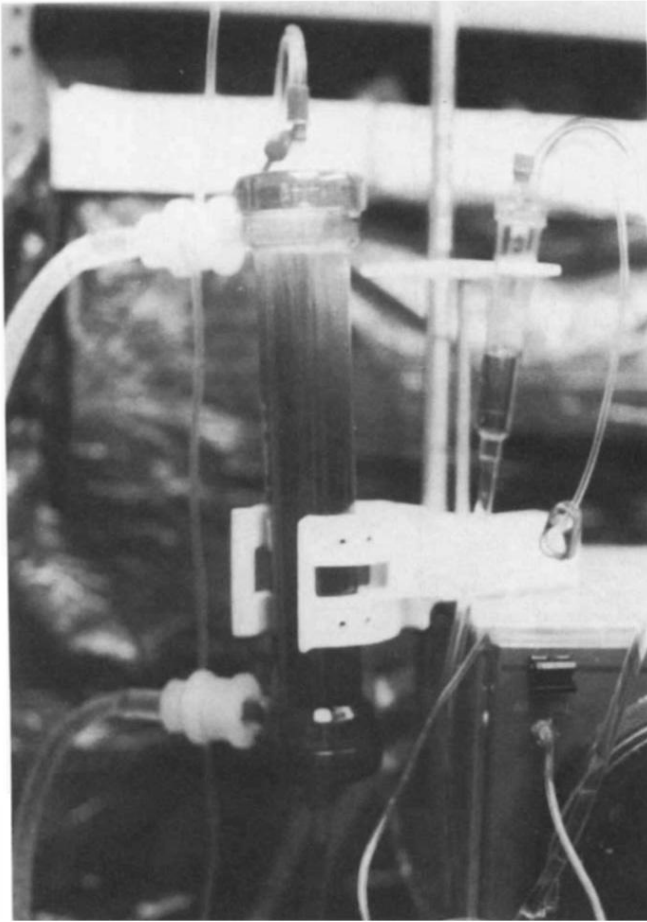


**Fig. 4.** Injection of methylene blue into the dialysate port of a dialyzer with markedly impaired urea clearances in vivo. There was marked maldistribution of flow with the path of the dye being confined to one side of the dialyzer.

2). The TCV of each lot of dialyzers, measured by the DRS 4 reprocessor, were not different after 15 reprocessing procedures (lot #1,  $84 \pm 1$  ml; lot #2,  $83 \pm 1$  ml). The TCV of the same dialyzers in lot #1 were  $84 \pm 1$  and lot #2,  $82 \pm 1$  ml, when measured manually.

Because the major impairment in clearances appeared to occur by the first five reprocessing treatments, serial clearances were performed after 0, 1, 3, and 5 reuses in seven dialyzers from lot #1. As shown in Figure 7, reprocessing a single time lead to a mean decline in clearances of 11% ( $218 \pm 9$  vs.  $195 \pm 7$  ml/min). After reprocessing five times, the clearance declined to  $151 \pm 16$  ml/min. It was also obvious that there was considerable variability in clearances of dialyzers in lot #1.

Because the dialyzers were soaked in 0.8% glutaraldehyde between each reprocessing procedure, we investigated the effect of soaking eight dialyzers in lot #1 in the same solution for a period of five days. As can be seen in Figure 8, soaking also led to a decline in clearance. The fall, from  $224 \pm 4$  to  $197 \pm 4$  ml/min, however, was not as great as that of reprocessing ( $P < 0.02$ ). Although glutaraldehyde may form polymers and

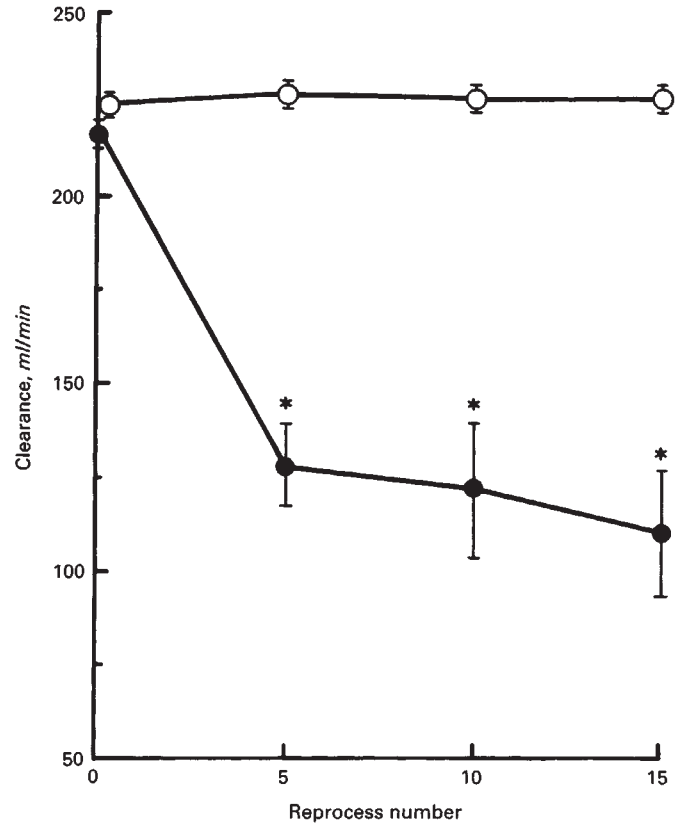


**Fig. 5.** Injection of methylene blue into the dialysate port of a dialyzer associated with intact urea clearances in vivo. Note the uniform pattern of flow of the dye as it traverses the dialyzer.

cause fiber adherence, it could also hydrate the fibers causing changes in their size or geometry. We therefore soaked eight dialyzers in standard dialysate for five days. The clearances decreased 11% from  $223 \pm 3$  to  $192 \pm 6$  ml/min (Fig. 8). The latter values were significantly less than control measurements ( $P < 0.001$ ) but greater than those measured after five daily reprocessing procedures ( $P < 0.02$ ). No changes in clearances due to soaking in dialysate were noted in lot #2 ( $226 \pm 1$  vs.  $223 \pm 2$  ml/min). Hence, the effects of the glutaraldehyde solution on dialyzer function may have resulted from hydration of the hollow fibers rather than a property unique to that compound.

#### Discussion

It is frequently stated in texts [8, 9] that clearances by dialyzer are unaffected by reuse if proper standards for rejection are followed. Ferrell et al [10], for example, found a good correlation between TCV and clearances. Gotch [11] noted a similar correlation. Others [12–14] were able to correlate UFR and clearance. We employed both these parameters as well as visual inspection and fiber leak but, nonetheless, encountered an epidemic of dialyzer dysfunction. Although Vanholder et al reported mild decreases in clearances in some dialyzers with up



**Fig. 6.** Serial conductivity clearances of dialyzers in a lot associated with low clearances in vivo (lot #1, ●) and of those from a lot with intact clearances (lot #2, ○). The clearances of unused dialyzers were the same in the two lots. However, following 5 reprocessing treatments, the clearances of dialyzers in lot #1 fell significantly ( $P < 0.001$ ) and continued to decline after 10 and 15 treatments. No changes in clearances were noted in the dialyzers from lot #2. All maneuvers were performed in vitro without exposure of the dialyzers to patients.

to 7 reuses [15], to the best of our knowledge, the severity and prevalence of the problem we encountered is unprecedented. It should be emphasized that our data concerns only dialyzers with cuprophane membranes and may not apply to other types of dialyzers. Although we do not believe that the type of disinfectant plays a significant role in causing dialyzer dysfunction, the findings also may not be relevant to reprocessing systems utilizing formaldehyde.

The etiology of the damage to the dialyzers was probably multifactorial. The in vitro and in vivo studies showed that three lots of dialyzers were adversely affected by reprocessing whereas other lots were not affected. The large variability in declining clearances in lot #1 may explain the lack of correlation between in vivo clearances and number of reuses. There were, however, good correlations between declines in in vivo and in vitro clearances in two separate lots of dialyzers. The findings of channeling in the severely affected dialyzers, may account, in part, for the absence of alterations in TCV or KUF in the dialyzers. One would think, a priori, that maldistribution of flow between blood and dialysate would have the potential to diminish clearances without affecting these parameters. The decrease in clearances following soaking dialyzers in lot #1 is of interest. It is postulated that wetting the fibers caused expan-

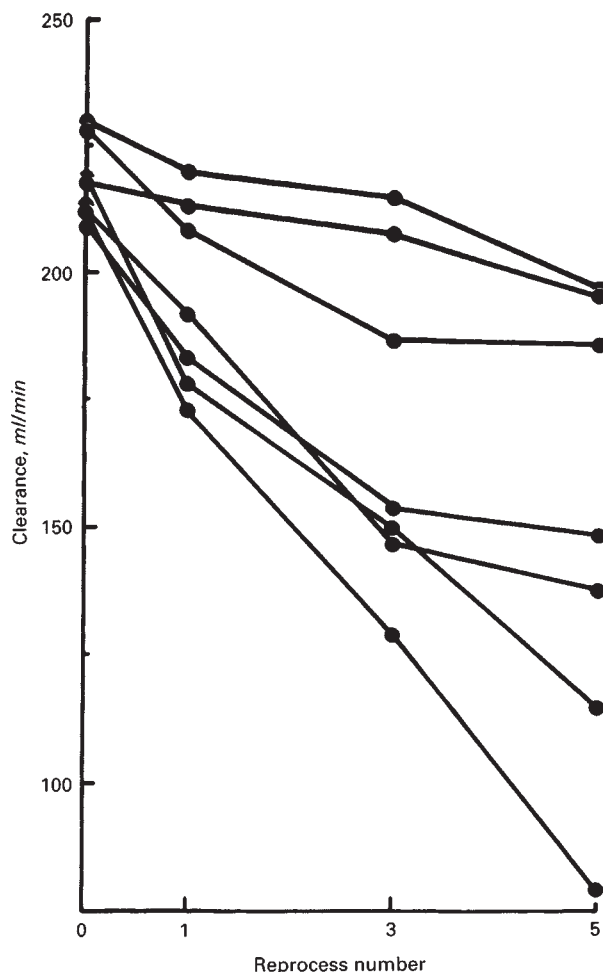


Fig. 7. Serial conductivity clearances in dialyzers from lot #1 exposed to 0, 1, 3, and 5 reprocessing treatments. A decline in clearances was noted in all dialyzers after one treatment which progressed following subsequent treatments.

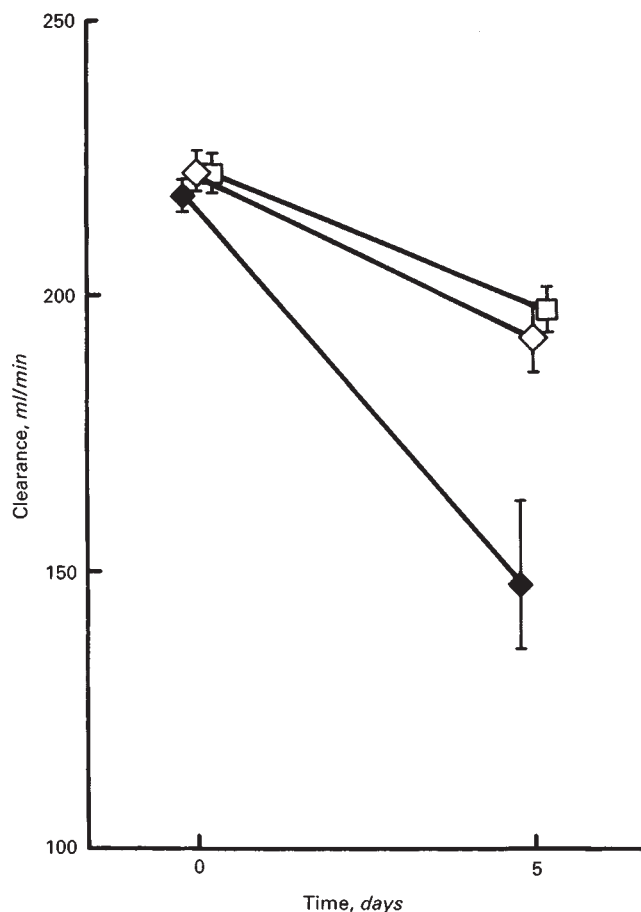


Fig. 8. The effects of soaking dialyzers from lot #1 in dialysate or glutaraldehyde on conductivity clearances. Symbols are: (□) soak in glutaraldehyde; (◇) soak in dialysate; (◆) reuse. After 5 days, soaking in either solution led to an 11% decline in clearance. This was less than that seen after 5 days of daily reprocessing with glutaraldehyde storage ( $P < 0.02$ ). There were no effects of soaking in either solution on clearances in dialyzers from lot #2 (data not shown).

sion and elongation. This, in turn, could predispose to channeling. The exact cause of the dialyzer malfunction is unknown. Conceivably, errors in fiber length, geometry or number could lead to distortion. Because reprocessing was associated with lower clearances than those of soaking in glutaraldehyde or dialysate, it is likely that it further potentiated fiber deformity in those predisposed dialyzers. This may have been due to the high negative transmembrane pressures present during the cleaning cycle. It should be noted, however, that the Seratronics reprocessing system utilizes 1200 mm Hg of pressure whereas the Renatron system employs 250 mm Hg. Nonetheless, reprocessing with either system appeared to decrease clearances in one lot to the same extent. This suggests that the degree of predisposition to develop dialyzer dysfunction during reprocessing may be of greater importance than the type of reprocessing system.

Reuse is generally a safe and reliable method to treat patients with renal failure [16]. Robson et al [17] report fewer episodes of hypotension, cramps, nausea or vomiting, headache, itching, chest pain and back pain when patients are dialyzed with reused dialyzers compared to those used for the first time. Presumably

these effects are due to decreased complement activation and neutropenia seen in reprocessed cuprophane dialyzers [18].

Until the prevalence of inapparent severe dialyzer dysfunction during reprocessing is known, any comprehensive recommendations concerning reprocessing beyond those of AAMI [19] would be ill-advised. Clearly, however, one should be aware of the potential for occurrence. Any unexplained worsening of patients' symptoms, chemistries, or urea kinetics warrant immediate investigation. In addition, spot checks of the in vitro clearances of reprocessed dialyzers should afford an additional level of safety.

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