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This information was provided with courtesy by all researchers listed.
**Clinical Performance of the Nipro ELISIOTM-190H Dialyzer in Hemodialysis and Hemodiafiltration**

### Introduction

The Nipro ELISIOTM-190H dialyzer is equipped with a new synthetic high-flux dialysis membrane named POLY-NEPHRON™. It is characterized by an optimized removal for small molecules as well as for low-molecular weight (LMW) proteins. In vitro studies have indicated that the performance of the Nipro ELISIOTM™-190H dialyzer must be superior to conventional high-flux filters. In a first clinical trial, this new dialyzer was compared to two reference filters. Its suitability for hemodialysis (HD) and online postdilution hemodialysis (HDF) was tested.

### Methods

In a prospective, randomized, cross-over study on eight maintenance dialysis patients (all male; age 56±12 years), the Nipro ELISIOTM™-190H dialyzer (referred as NE; Nipro Corporation, Japan; 1.9 m²) was compared to the two synthetic high-flux reference dialyzers Fresenius FX80 (referred as FX; Helexone® (polysulfone), Fresenius Medical Care AG; 1.8 m²) and Gambro Polyflux® 170H (referred as GP; Polyamix®, Gambro Hechingen; 1.7 m²). Each patient underwent three HD and three online postdilution HDF treatments. Blood and dialysate flow rates were set at 400 and 700 mL/min, respectively. In HDF, the substitution flow rate was set at 80 mL/min resulting in an effective dialysate flow rate of 620 mL/min. The treatment time was 240±0 min. During each third HD and HDF treatment, instantaneous plasma clearances (K) and reduction rates (RR) of small solutes (urea, creatinine, phosphate) and LMW proteins (β2-m, 11,800 Da; cystatin c, 13,400 Da; myoglobin, 17,800 Da; retinol-binding protein, 21,200 Da; α1-microglobulin, 30,000 Da) as well as biocompatibility parameters (WBC, platelets, C5a, thrombin-antithrombin III (TAT)) were measured.

### Results

K for small solutes (urea, creatinine, phosphate) were not statistically different between the dialyzers. For the LMW proteins β2-m (Figure 1), cystatin c and myoglobin (Figure 2 and 3), compared to FX and GP, NE obtained by far higher instantaneous plasma clearances at 30 and 180 min as well as reduction ratios in both therapy modes. With higher molecular weight, the differences between NE and the references increased. None of the dialyzers led to clinically considerable removal of retinol-binding protein or α1-microglobulin. The albumin loss was slightly higher with NE being 0.52±0.13 in HD and 1.61±0.63 g in HDF (FX and GP in HDF 1.15±0.38 and 1.42±0.24 g). The biocompatibility parameters were excellent and not different for the three dialyzers. Only a typical minor leukocyte drop (Figure 4) and complement C5a increase was observed between 5 and 10 min for all dialyzers. There was virtually no activation of coagulation as indicated by low and stable TAT values.

### Conclusion

In this first clinical trial, the new Nipro ELISIOTM™-190H dialyzer was easy to handle and showed perfect suitability for both HD and HDF. Independently of the treatment mode, it demonstrated much better performances than the reference filters with regard to LMW protein removal. This superiority in LMW protein removal was not at the expense of albumin loss, which, indeed, was higher than FX and GP but remained by far within clinically accepted limits. The biocompatibility parameters were in the typical range for a modern synthetic dialyzer and must be regarded as excellent. The performance of the new ELISIOTM™ dialyzer can be considered as a contribution to more adequate dialysis and its chronic use may have beneficial effects on patient outcome.
The Company Nipro has developed a new synthetic dialyzer, the ELISIO™-H series, equipped with a new synthetic high-flux membrane named POLYNEPHRON™. In vitro studies have shown optimized clearances for small molecules as well as for low-molecular weight (LMW) proteins in the absence of significant albumin loss. In this study we wanted to confirm the excellent biocompatibility of this dialyzer and study its influence on inflammatory and nutritional parameters in a population of chronic HD patients, treated by on-line pre-dilution HDF.

Methods

In a prospective single center study on ten maintenance dialysis patients (mean age 77 years, 6 men, number of years in HD:6.8), the Nipro ELISIO™-190H dialyzer (UF coeff: 76 mL/h/mmHg; Nipro Corporation, Japan; 1.9 m²) was evaluated. Each patient underwent 13 online pre-dilution ultrapure HDF treatments. Blood and dialysate flow rates were set at 300 and 800 mL/min, respectively. In predilution-HDF, the substitution flow rate was set at 150 mL/min. The treatment time was 240±0 min. Plasma samples were taken at t=0, at t=240 min or at both time intervals during each first and 13th HDF treatment (hereafter denoted T1 and T13) for the determination of CRP, IL-6, IL-10, TNF-α, urea, hemoglobin and albumin. Samples were also taken at 30min for the determination of biocompatibility parameters WBC and C3 and at various time intervals for the determination of IL-6, IL-10 and TNF-α in the dialysate/ultrafiltrate. Kt/V’s were measured according to the formula of Basile et al.

Results

All treatments were well tolerated and no adverse events were observed. The results of the classical parameters pointed to an excellent biocompatibility: WBC and C3 remained stable after the first 30 min of the treatment. CRP did not increase during the treatment neither at T1 nor at T13 (see Fig. 1). IL-6 (MW 28,000Da, pro-inflammatory cytokine) did not increase during the treatment nor between T1 and T13 (see Fig. 2). The anti-inflammatory cytokine IL-10 (MW: 19,000Da) increases significantly during the first treatment and also between T1 (at t0) and T13 (at t0). Plasma TNF-α levels were below the detection limit. To check whether cytokines leak out during the pre-HDF treatment, IL-6 and IL-10 were also measured in the dialysate. Unfortunately, all concentrations were below detection limit. Performance of the Elisio-190H about small molecules clearances was excellent (Table 1). Plasma albumin, hemoglobin levels and EPO doses didn’t change after one month (Table 2).

Discussion

In this preliminary clinical study, the new Nipro ELISIO™-190H dialyzer is well tolerated with perfect suitability for predilution online HDF. The results of classical parameters (WBC and C3) point to an excellent biocompatibility. The inflammatory parameters (CRP and IL-6) do not increase during the treatments nor after one month. IL-6 and IL-10 however could not be detected in the dialysate, suggesting either that these LMW proteins are not removed, or more probably are under the detection threshold of the method of measurement due to their large dilution in the 57 L/h of dialysate collected.

The performance of the new dialyzer for the removal of small molecules like urea is excellent. The plasma albumin conc. does not change after one month of treatment, suggesting that, despite the highly UF coefficient of the membrane, there is no important leakage of albumin. Patient Hb concentrations and needs for EPO remain constant after one month suggesting also the good tolerance of the dialyzer. These promising data need to be confirmed in a multicenter study for longer period of time.
In-Vivo Evaluation of Nipro ELISIO™ Dialyzer
= Comparison between HD and post OL-HDF =

**Objective**

The objectives of this prospective, randomized and comparative study (in two parallel groups) were to compare the Nipro ELISIO™-210H dialyzer between hemodialysis (HD) and on-line hemodiafiltration (HDF) techniques in terms of different parameters including dialysis efficacy and biocompatibility after 4 months of treatment.

**Methods**

Twenty patients were enrolled in this study. All patients were dialyzed with the ELISIO™-210H dialyzer during the entire study. After a one-month wash-out period all with HD, patients were randomly assigned to two treatment groups, “HD” (n=10) and “HDF” (n=10) for a four-month period.

After the wash-out period, dialysis conditions remained unchanged for each patient (3 sessions/week for 4 months; 3 to 4 hours/session; with a blood flow QB=300-400mL/min, ultrapure bicarbonate buffered dialysate, dialysate flow QD=500-700mL/min, ultrafiltrate flow QF=110-120mL/min [adjusted to weight loss], substitution flow QF=100mL/min [post-dilution]). At time points M0, M1, M2, M3 and M4 (after 0, 1, 2, 3 and 4 months of treatment respectively), removal rates (urea, creatinine and beta2-microglobulin [B2m]), instant clearances of urea and creatinine after 60 min of dialysis, dialysis dose and dialysate losses of albumin were measured. At M0 (= randomization) the removal of inflammatory, oxidative stress, coagulation and apoptosis markers was determined. At M4 (4 months of treatment after randomization) the evolution of inflammatory, nutritional, oxidative stress, coagulation, apoptosis, cell activation and bone disease markers were observed. The comparisons between the HD and HDF groups were performed using Mann-Whitney non-parametric tests. Friedman and sign tests were used to compare variables over the time within each group.

**Results**

The ELISIO™-210H dialyzer was well tolerated by all patients, both in HD and HDF during the entire study period (5 months including the wash-out period). The urea Kt/V demonstrated a tendency to increase between M0 and M4, in both HD and HDF (Fig. 1). Albumin losses into the dialysate were higher in HDF than in HD, but most of the values were below 1.0 g/session in HDF and below 0.5 g/session in HD (Fig. 2).

A significant increase in beta2m reduction rate was observed in the HDF compared to the HD group at M1, M3 and M4 (Fig. 3). A significant decrease in Time Average Concentration of beta2m was observed in HDF compared to HD at M1, M2, M3 and M4 (Fig. 4).

Regarding biocompatibility parameters, no significant difference was observed between both techniques in particular in terms of inflammation. Indeed, CRP level did not change during the entire study between HD and HDF even though high efficiency (high volume) was performed in HDF (not shown).

**Conclusion**

The Nipro ELISIO™-210H dialyzer was safely used in all the patients included in this study. Use of this dialyzer was associated with an excellent removal of beta2-microglobulin whatever the technique used (HD or HDF) and an excellent biocompatibility profile was achieved with HDF technique.

By courtesy of Prof. Bernard CANAUD, CHRU Lapeyronie, Montpellier, FRANCE
Consequences on renal anemia of two synthetic high-flux dialyzers

Introduction

Membrane biocompatibility and performance have long been thought to be relevant to renal anemia. This study compared the consequences on renal anemia of 2 synthetic high-flux dialyzers during 6 months. Optimal renal replacement therapy could play a role in correcting the anemia by removing small and possible medium-to-large molecules that inhibit erythropoesis. The 2 dialyzers were a standard polysulphone dialyzer (HF80S) and the ELISIO ™-190H dialyzer, based on the new Polynephron™ membrane. We wanted to evaluate the anemia improvement effects in both dialyzer groups.

Methods

In a prospective, randomized study on twenty maintenance dialysis patients (11 male; 9 female; mean age: 72 years), the Nipro ELISIO™-190H dialyzer (referred to as ELISIO; Nipro Corporation; Japan; 1.9 m²) was compared to a synthetic high-flux reference dialyzer HF80S (referred to as HF), polysulphone, Fresenius Medical Care AG, 1.8 m². Ten patients were treated for 6 months with the ELISIO dialyzer and the other ten with the HF. There were 2 dropouts in each group. Each patient underwent three HD treatments per week. Blood and dialysate flow rates were set at 400 and 700 mL/min, respectively. The treatment time was 240±21.9 min. At T=0 and then every month, during each third HD treatment, instantaneous plasma clearances and reduction rates of small solutes (urea, creatinin, phosphate), pre-dialysis levels of β2-microglobulin (11.800 Da), hematological parameters (haemoglobin level, haematocrit), serum iron, TIBC, and ferritin were measured. The anemia improvement effects were evaluated by calculating the ESA doses and the EPO Resistance Index.

Results

Kt/V increased between T0 and T6 (after 6 months) in both groups but the increase was not significant (not shown). β2-microglobulin pre-dialysis levels decreased significantly between T0 and T6 in both dialyzer groups (see table 1). The haemoglobin levels increased between T0 and T6 (Fig.1); this increase was significant (p=0.006) only for the ELISIO-group. ESA (Erythropoesis Stimulating Agent) did not change significantly during the 6-month period (Fig. 2). The EPO Resistance index decreased by 22.7% between T0 and T6 in the ELISIO-group and increased by 14% in the HF-group, but these changes were not statistically significant (Fig.3).

Conclusion

Haemoglobin outcome improved overall during the study; the improvement after 6 months was significant for the ELISIO-group only. ESA dose was not significantly different after 6 months compared to baseline in either group. The same holds for the EPO Resistance Index, although a 22.7% decrease was observed in the ELISIO-group and a 14% increase in the HF group.

By courtesy of Dr. Viganò, Dr. Pontoriero, Dr. Di Filippo and Prof. Locatelli, Lecco (Italy), 2009 to April 2010
INFLUENCE OF THE NIPRO ELISIO™-190H ON THE PROINFLAMMATORY ACTIVITY OF CIRCULATING MONONUCLEAR CELLS

Introduction

Haemodialysis (HD) patients have a proinflammatory state with high cardiovascular risk. One of the mechanisms involved in the genesis of this vascular damage seems to be the degree of activation of circulating cells, and biocompatibility of dialysis membranes could influence the inflammatory activity of these cells. In this study we compare the effect of the new dialyzer Nipro ELISIO™-190H (ELISIO) with a conventional high flux polysulphone (PS) on the proinflammatory activity of peripheral blood mononuclear cells (PBMC) of hemodialyzed patients.

Methods

Ten patients were included in the study. Eight were dialyzed with an arterio-venous fistula and two with central catheter. Mean blood flow rate (Qb) was 325 mL/min. At baseline, all patients were on HD with high flux PS membranes (1.8 m²). After that, the patients were sequentially treated with two different membranes as follows: five patients were treated initially with PS and five patients with ELISIO for two weeks, and then dialyzers were interchanged for two additional weeks.

Blood extraction was done pre and post HD during the first session with the different membranes (acute effect) and pre HD after two weeks with the membrane analyzed (chronic effect). PBMC were isolated from total blood with the Ficoll method, and incubated with standard cultured endothelial cells (EC). The adhesion of PBMC to EC was measured by flow cytometry using the antibody CD14-PE, and PBMC-dependent endothelial damage was analyzed by measuring the release of LDH into the incubation media.

Results

After just one session of HD with the different membranes, no differences in reduction rate of urea (ELISIO: 0.64 ± 0.08; PS: 0.66 ± 0.097, p= 0.86), creatinine (ELISIO: 0.58 ± 0.092; PS: 0.57 ± 0.163, p= 0.64) and β2 microglobuline (PS: 0.47 ± 0.27, ELISIO: 0.58 ± 0.12, p = 0.6) were found. After two weeks of treatment with both membranes, no differences on serum low and median molecular weigh metabolites: (urea, creatinine and β2 microglobuline) were found. Neither PS nor ELISIO induced a significant activation of PBMC, regarding their ability to interact and to damage EC (see the figure below).

Conclusion

The biocompatibility of ELISIO was comparable to that of PS, regarding the ability of the membranes to induce the proinflammatory activity of circulating mononuclear cells. Additional studies, with more patients and for longer periods of time, are being performed to confirm this excellent biocompatibility.

From courtesy of Dr. Diego Rodriguez Puyol, Hosp. Universitario Príncipe de Asturias, SPAIN
Middle molecule retention has been reported to reduce survival for long term haemodialysis patients. To increase middle molecule clearances, such as β2-microglobulin, high flux dialyzers with increased internal filtration have been developed. However increased internal filtration may increase the risk of dialyzer clotting due to haemoconcentration and loss of anticoagulant. To investigate this possibility, we studied plasma markers of coagulation, platelet, white cell and endothelial activation during dialysis sessions with ELISIO 210H and FX100, dialyzers developed to increase internal filtration.

Methods

15 patients (53.3% male; age 66.1±2.1 years) attending for thrice weekly outpatient hemodialysis (HD) who had been dialyzing with polysulphone and polyvinylpyrrolidone (PVP) dialyzers (Helixone®, FX100, Fresenius, Bad Homburg, Germany) were studied during a midweek dialysis session and then after 12 weeks of HD with polyethersulphone and PVP dialyzers (Polynephron™ ELISIO-210H, Nipro Corporation, Osaka, Japan). Measured mean flow rate were 288±5.4 ml/min (FX100) vs 285.5±3.7 ml/min (ELISIO). Dialyse flow was maintained at 800 ml/min. The treatment time was 4.16±0.07 hours. 12 patients were anticoagulated with LMWH (Tinzaparin®), mean dose 2464±383 IU vs 2643±372 IU, administered into the venous limb of the circuit, two patients used no anticoagulant and one patient lepirudin. Both the dialyzers and venous air detector chambers were observed during and at the end of the dialysis session for presence of clot formation, and assessed by a visual analogue scale. In addition to standard investigations (coagulation screen, full blood count and albumin level), Tinzaparin® levels, factor (F) VIII:C, von Willebrand factor antigen (VWF:Ag), VWF propeptide (VWF:pp), thrombin anti-thrombin (TAT) complexes, prothrombin fragment 1+2 and D-dimers were measured. Thrombin generation assays were carried out on double spun plasma triggered with 5pM reagent using the calibrated automated thrombogram (CAT) method. The endogenous thrombin potential (ETP) was generated by dedicated software. The CTAD plasma samples were used for the measurement of platelet activation markers (b-thromboglobulin (b-TG), platelet factor 4 (PF4) and soluble (s) P-selectin. Plasma levels of the following adhesion molecules were determined by ELISA: soluble (s) CD40 ligand, sICAM-1, sVCAM-1 and sE selectin. Results are expressed as mean ± standard deviation, or median and interquartile range, or percentage. Statistical analysis was by students’ paired t test for parametric data and by the Wilcoxon rank sum pair test for nonparametric data, with Bonferroni correction where appropriate.

Results

1. All dialysis sessions were completed satisfactorily, with no significant clotting. External examination of the dialyzers did not show any clotting in the outer fibres or header, and no clot formed in the venous air detector.
2. Routine laboratory clotting tests (PT, APTT and TT) did not change significantly with dialysis, and were not different between the two dialyzers.
3. At the start of dialysis, patients had evidence of activation of coagulation (with increased factor VIII:C, VWF:Ag, VWF:pp, TAT and F1+2), and evidence of increased fibrinolysis (raised D-dimers).
4. Coagulation activation, as measured by TATs and F1+2, at the end of the dialysis session was less with the ELISIO dialyzer than with the FX dialyzer. (see Fig. 1 and 2)
5. There was no difference in Tinzaparin® levels at end of dialysis session using either dialyzer, as shown by anti-Xa activity - 0.145±0.027 IU/ml (FX) vs 0.11±0.017 IU/ml (ELISIO), showing that there were no significant LMWH losses during the treatment.
6. Prior to dialysis, patients showed evidence of platelet activation with increased PF4 and b-TG levels. However, PF4 and b-TG levels did not increase further with dialysis, or with either dialyzer, but plasma sP-selectin did increase with dialysis suggesting platelet activation, as P-selectin is released from intracytoplasmatic platelet granules.

Conclusion

All dialysis sessions were completed satisfactorily with no significant clotting. Despite adequate dialysis (Kt/V 1.47±0.06), haemodialysis patients have an inflammatory phenotype, characterized by increased activation of coagulation, platelets and fibrinolysis, but the dialyzers did not significantly increase platelet activation or thrombin generation. There was no difference in anti-Xa activity at the end of the dialysis session with the membranes, suggesting that there was no additional loss of low molecular weight heparin with the ELISIO and the FX dialyzers. Coagulation activation, as measured by TATs and F1+2, at the end of the dialysis session was less with the ELISIO dialyzer. Dialyzers designed to increase internal filtration and convective transport did not significantly lead to increased LMWH losses or increased risk of thrombosis.
**Clinical Performance of the Nipro ELISIO™-170M Dialyzer in Hemodialysis Treatment**

**Introduction**

The Nipro ELISIO™-170M dialyzer is equipped with a new synthetic mid-flux dialysis membrane named POLYNEPHRON™ (Nipro-made). It was designed to deliver a mild dialysis treatment with high removal for small molecules. In this study the new ELISIO™-170M dialyzer is compared to the market-available high performance model, Nipro PES-170DS dialyzer in terms of solute removal as well as biocompatibility.

**Methods**

In a prospective, randomized study on eight maintenance dialysis patients (4 male, 4 female; mean age 65±21 years), the Nipro ELISIO™-170M dialyzer (POLYNEPHRON™, Kuf=22mL/hr/mmHg; 1.7 m², hereafter called EL-M) was compared to the synthetic reference dialyzer Nipro PES-170DS (DIAPES®, Kuf=46 mL/hr/mmHg; 1.7 m²; hereafter called PES-DS). Each patient underwent three HD treatments for each dialyzer. Blood and dialysate flow rates were set at 300 and 500 mL/min, respectively. The treatment time was 240 min. During each third HD treatment, instantaneous plasma clearances \(K\) and reduction rates \(RR\) of small solutes (urea\([60 \text{ Da}]\), creatinine\([113 \text{ Da}]\), phosphate\([96 \text{ Da}]\)) and middle molecules (osteocalcin\([5,800 \text{ Da}]\) and \(\beta_2\)-microglobulin\([11,800 \text{ Da}]\)), and were measured, as well as we were measured biocompatibility and anti-coagulation parameters (WBC, platelets, C5a, thrombin-antithrombin III (TAT)). The albumin \((67,000 \text{ Da})\) loss was determined in continuously collected dialysate. For statistical analysis, a two-way ANOVA was performed.

**Results**

\(K\) of EL-M for urea was statistically significant higher, while \(K\) for creatinin was not statistically different to each other. The deterioration in clearance over time was relatively low for the two dialyzers (Figure 1). For the removal rate of osteocalcin, values of PES-DS were superior. \(\beta2m\) removal rate was 64% for PES-DS and negligible for EL-M. The albumin loss for PES-DS was 2.3g, while that of EL-M was under detection limit (Figure 2). The biocompatibility parameters C5a and WBC showed time courses typical for hemocompatible membranes for the two dialyzers. There was no statistical significant difference between the two dialyzers for C5a after 5 and 15 min nor for WBC (difference of pre vs. 15 min in Figure 3). Heparin requirement was the same for the two dialyzers since the coagulation related parameters platelet count and TAT (Figure 4) were not significantly different (after 30 and 240 min).

**Conclusion**

In this first clinical trial, the new Nipro ELISIO™-170M dialyzer was easy to handle, and all the patients tolerated all treatments without any side effect or adverse event. Overall in ease of handling, EL-M dialyzers did not perform worse than the reference dialyzers PES-DS. For small molecule clearances, EL-M removes comparable solutes in spite of relatively lower ultrafiltration rate than PES-DS. The biocompatibility parameters were in the typical range for a modern synthetic dialyzer and must be regarded as excellent. The performance of the new ELISIO™-M dialyzer can be considered as a contribution to more adequate dialysis (higher small molecule clearances), not sacrificing the albumin amount.

Clinical study in Germany, November to December 2008
Evaluation of the new Nipro ELISIO™-17H in comparison with two reference filters

Introduction

The Nipro ELISIO™-17H dialyzer is equipped with a new synthetic high-flux dialysis membrane named POLYNEPHRON™. It is characterized by an optimized removal for small molecules as well as for low-molecular weight (LMW) proteins, while retaining albumin. This dialyzer features a new polypropylene housing and headers and is completely Bispheanol-A free. The purpose of this evaluation was to evaluate the biocompatibility, the thrombogenicity and the clearance properties in hemodialysis in comparison with 2 reference dialyzers.

Results

Clearances for β₂m and myoglobin were significantly higher with the ELISIO-17H than with the GP170H and the FX80 (Fig. 1). Removal rates (RRs) for the small molecules (urea, creatinine, phosphate) did not differ significantly between the dialyzers. For the RRs of the larger molecules (β₂m and myoglobin), the ELISIO-17H was superior to the other 2 dialyzers (not shown). None of the dialyzers led to a measurable RR for albumin (66,000 Da). The biocompatibility parameters (WBC Count and C5a) were not different for the three dialyzers. PMN elastase was comparable for ELISIO and FX80, but larger for GP170H. Thrombogenicity parameters were also analyzed. No significant differences in platelet count were found between the dialyzers. There was a small but significant increase in TAT during dialysis for all dialyzers, but this was comparable for ELISIO and FX80, but larger for GP170H. Thrombogenicity parameters were also analyzed. No significant differences in platelet count were found between the dialyzers. There was a small but significant increase in TAT during dialysis for all dialyzers, but this increase tended to be the smallest for the ELISIO. Permanently clotted fibers on the dialyzer surface were counted and judged by means of a grading. The ELISIO-17H showed the smallest number of such permanently clotted fibers. The ELISIO-17H can be regarded to have a significantly lower thrombogenicity compared with the GP170H.

Conclusion

Concerning the small molecule clearance data, the ELISIO-17H proved superior to the FX dialyzer. For larger molecules (β₂m and myoglobin), the ELISIO-17H was significantly more efficient than the Polyflux 170H and the FX80. Similarly, the removal rates for β₂m and myoglobin proved the superiority of the ELISIO-17H. For all dialyzer types, no RR of albumin was detected under the HD conditions used.

Concerning hemocompatibility, no significant differences were observed between the three dialyzers studied with respect to the WBC counts and complement activation. The activation of pmn-elastase was comparable for the ELISIO-17H and the FX80, but larger for the Polyflux 170H. The thrombogenicity judged by platelet count, TAT and the estimation of residual blood was the lowest for the ELISIO, whereas the Polyflux showed a comparatively higher thrombogenicity.

Clinical study in Germany, February to March 2010