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Introduction

The accumulation of small and middle molecular weight uremic solutes is associated with increased mortality risk of patients with end-stage renal disease. Therefore, hemodialyzers are designed to eliminate uremic toxins during dialysis treatment. The dialyzer's membrane is mainly responsible for the selective sieving of molecules. While clearance of uremic toxins of medium molecular size, such as β 2-microglobulin (11.8 kDa) is desired, a permeability cut-off should be maintained to prevent the concomitant loss of essential proteins such as albumin (66 kDa) during hemodiafiltration (HDF).

FX CorAL is a novel dialyzer with increased polyvinylpyrrolidone (PVP) content on its blood-side surface. To prevent PVP oxidation and elution, it is stabilized with a small amount of α -tocopherol.

This compendium summarizes key papers, abstracts and posters with evidence from laboratory, hemocompatibility clinical and epidemiological studies investigating the use of the **FX CorAL** membrane.

Randomized investigation of increased dialyzer membrane hydrophilicity on hemocompatibility and performance

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Ehlerding et al. BMC Nephrol. 2024 Jul 10;25(1):220

Randomized investigation of increased dialyzer membrane hydrophilicity on hemocompatibility and performance

Ehlerding et al. BMC Nephrol. 2024 Jul 10;25(1):220

Background

Dialyzers play a key role in removing middle-sized uremic toxins like β 2-microglobulin, which are linked to mortality in hemodialysis patients.

Hemocompatibility and performance are crucial factors, with synthetic polymer membranes such as the polysulfone **FX CorAL** designed to achieve these criteria.

By incorporating **higher PVP content** stabilized with α -tocopherol, the membrane achieves **greater hydrophilicity** and **resistance to oxidative stress**.

Objective

This study investigated the difference between **FX CorAL 600** and two other high-flux dialyzers (FX CorDiax 600 and xevonta Hi 15) in regard to:

- **Performance** (RR and clearance of β 2-m and Myoglobin)
- **Hemocompatibility** (markers of complement, cell, and platelet activation)
- **Patient well-being** and **safety** (PROs and albumin retention)

Randomized investigation of increased dialyzer membrane hydrophilicity on hemocompatibility and performance

Ehlerding et al. BMC Nephrol. 2024 Jul 10;25(1):220

Methodology

This multicenter, crossover study randomized stable post-dilution HDF patients (76 analysed as ITT and 70 as PP) to **FX CorAL 600**, FX CorDiax 600 and xevonta Hi 15 for 4 weeks each.

Primary Outcome

β 2-m RR, with non-inferiority and superiority of **FX CorAL** assessed

Secondary Outcomes

- Clearance of small and middle molecules
- Hemocompatibility profiles
- PROs and safety

Randomized investigation of increased dialyzer membrane hydrophilicity on hemocompatibility and performance

Ehlerding et al. BMC Nephrol. 2024 Jul 10;25(1):220

Results

Primary Outcome

FX CorAL has shown:

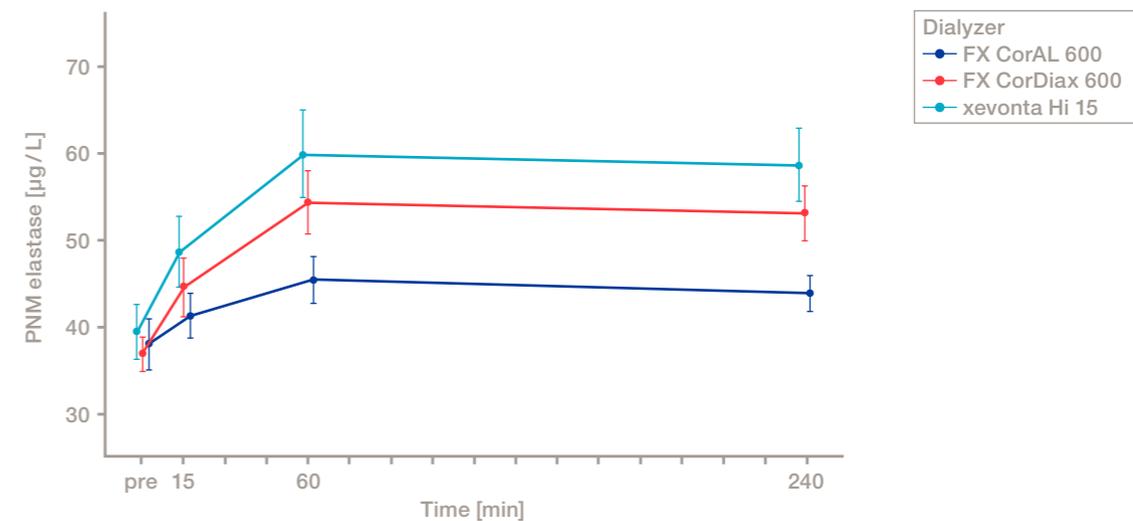
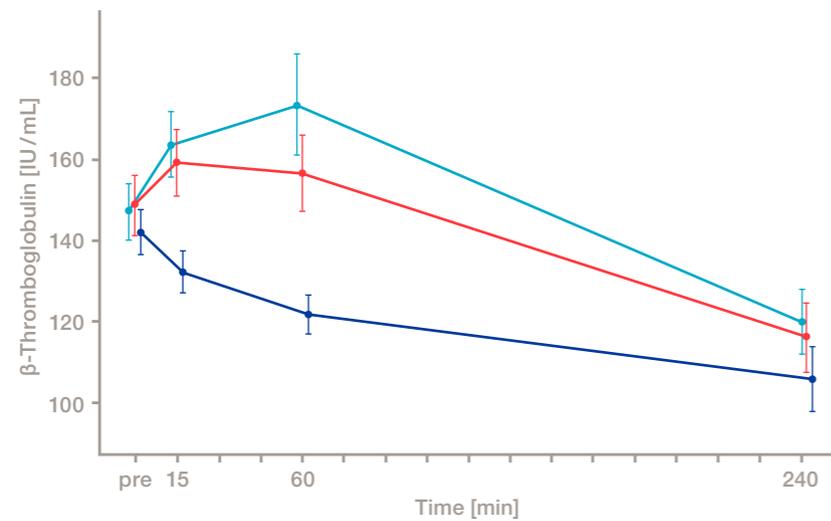
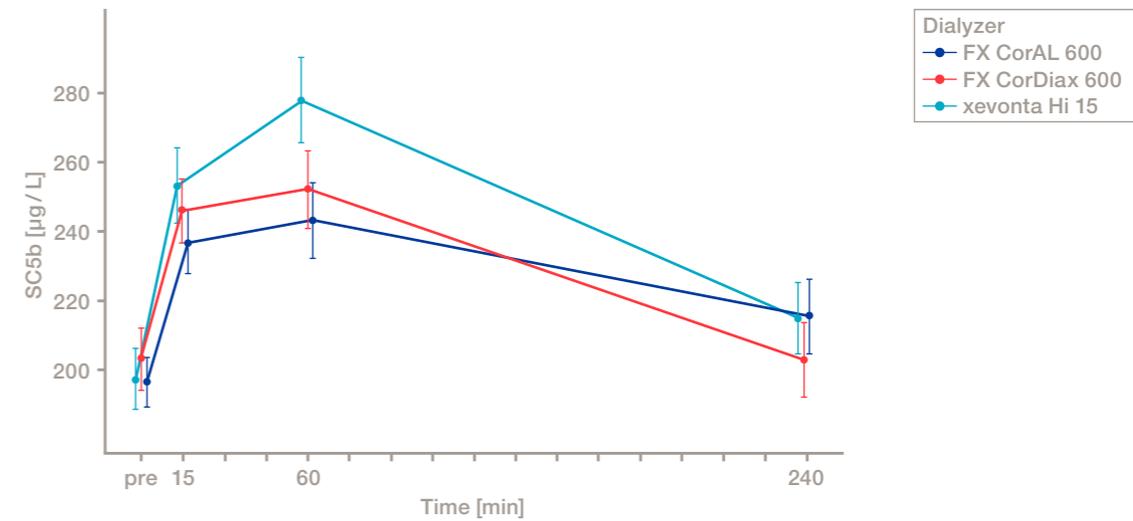
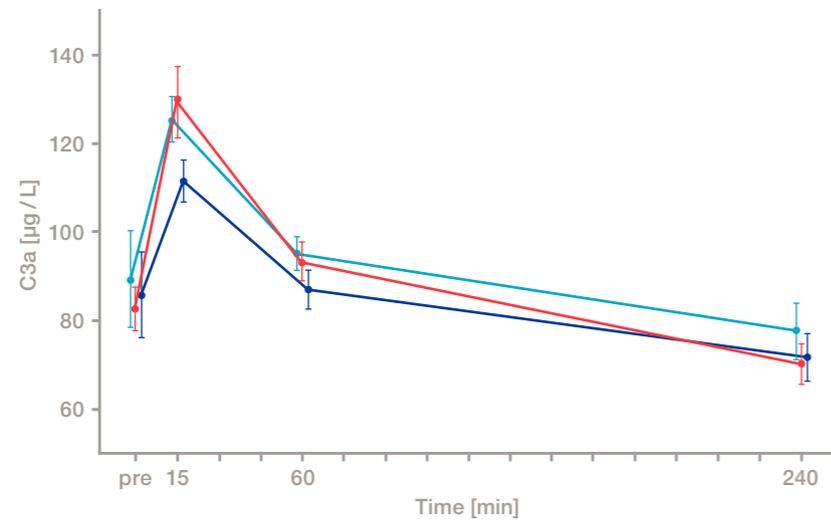
- The highest β 2-m RR (76.28%)
- Significant non-inferiority to both comparators
- Significant superiority to xevonta Hi 15

Secondary Outcomes

- **Lowest** complement, PMN elastase, LTB-4, β 2-TG **activation for FX CorAL**
- **Similar levels** of **oxidative stress** markers between comparators
- No differences in PROs or overall adverse events numbers between dialyzers

Randomized investigation of increased dialyzer membrane hydrophilicity on hemocompatibility and performance

Ehlerding et al. BMC Nephrol. 2024 Jul 10;25(1):220



Randomized investigation of increased dialyzer membrane hydrophilicity on hemocompatibility and performance

Ehlerding et al. BMC Nephrol. 2024 Jul 10;25(1):220

Conclusions

- The **FX CorAL** dialyzer exhibited **superior performance** in middle molecule removal and reduced complement, leukocyte, and platelet activation compared to its counterparts.
- These findings suggest that the **hydrophilic membrane** design could help **address inflammation** and **thrombosis, reducing cardiovascular risks** in hemodialysis patients.
- Though patient-reported outcomes showed no significant differences, the study supports the **potential of FX CorAL to improve clinical outcomes**. Long-term investigations are needed to confirm its impact on cardiovascular health and mortality.



Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

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Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Background

Middle molecules such as β 2-microglobulin are **key contributors to ESRD-related complications** and **require effective removal** during HD and HDF to improve patient outcomes.

The **FX CorAL** dialyzer, featuring a **hydrophilic membrane with enhanced PVP**, has demonstrated **superior performance** by minimizing protein adsorption and maintaining consistent clearance rates. These attributes are particularly beneficial in high-volume HDF, where membrane efficiency directly impacts treatment success.

Objective

This in vitro study examines, for the first time, the **role of hydrophilic membrane modifications** in the **FX CorAL** dialyzer in **maintaining β 2-microglobulin clearance and filtration efficiency after protein adsorption**.

These findings offer new perspectives on how advanced membrane designs may enhance dialysis treatment effectiveness.

Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Methodology

In this study, **FX CorAL** was compared to eight further dialyzers, containing synthetic (polysulfone- or polyether-sulfone-based) or cellulose-based membranes, regarding:

- Impact of Protein Adsorption on Middle Molecule Clearance
- Impact of Protein Adsorption on Filtration Performance



Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Results

Impact of Protein Adsorption on Middle Molecule Clearance

The results confirmed previous findings that **protein adsorption reduces the performance of dialysis membranes**, especially in the first 30 min of treatment.

Moreover, the **reduction in performance depends on the molecular weight** of the respective molecule, as the adsorption of plasma proteins to the membrane has a stronger effect on larger proteins than on smaller.

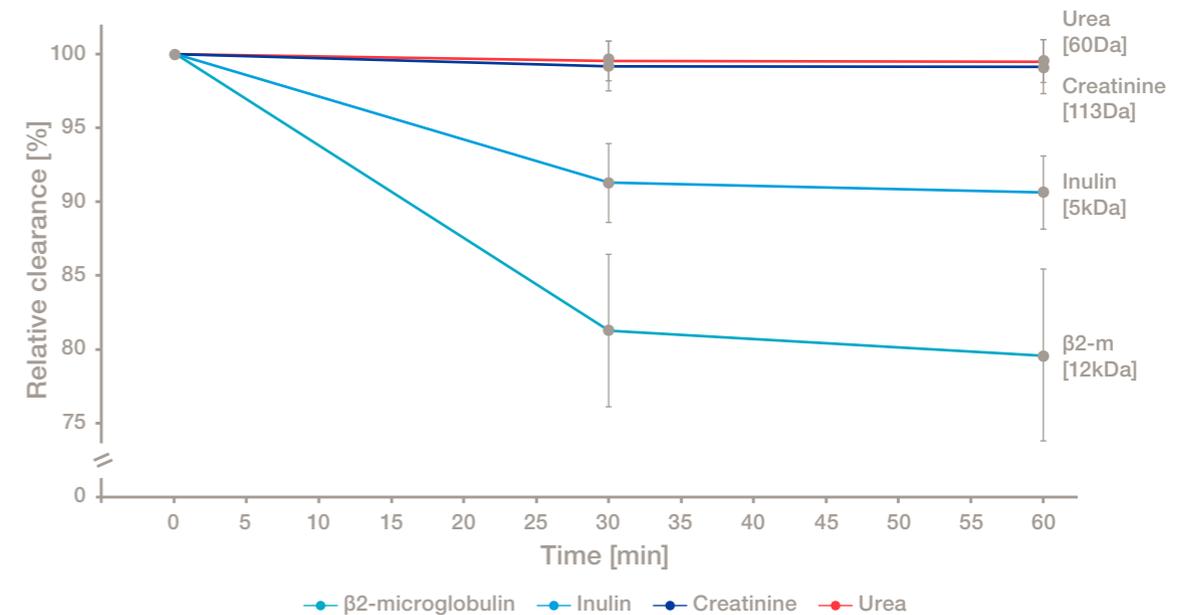


Figure 1. Reduction in β 2-microglobulin, inulin, creatinine, and urea clearances after protein adsorption to the membrane. Clearances were measured before as well as after 30 min and 60 min plasma recirculation. Displayed is the mean \pm SD clearance for all dialyzers tested relative to the initial measurement (before recirculation).

Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Results

Impact of Protein Adsorption on Middle Molecule Clearance

- Initial **β2-microglobulin clearance** (0 min) was **highest** for the three polysulfone-based dialyzers **FX CorAL** (47.2 ± 3.4 mL/min/m²), FX CorDiax (48.1 ± 0.7 mL/min/m²; $p = 0.997$ vs. **FX CorAL**) and xevonta (43.9 ± 3.0 mL/min/m²; $p = 0.432$).
- The **FX CorAL** (15.1%), **Revaclear** (13.4%) and **Cellentia** (14.2%) showed the **lowest decrease in β2-microglobulin clearance over 60 min.**
- **After 60 min of protein fouling, the FX CorAL** showed the **highest β2-microglobulin clearance** (40.0 ± 1.3 mL/min/m²), which was statistically significant in comparison to all other investigated dialyzers, except for the FX CorDiax dialyzer (38.6 ± 1.4 mL/min/m²; $p = 0.716$).

Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

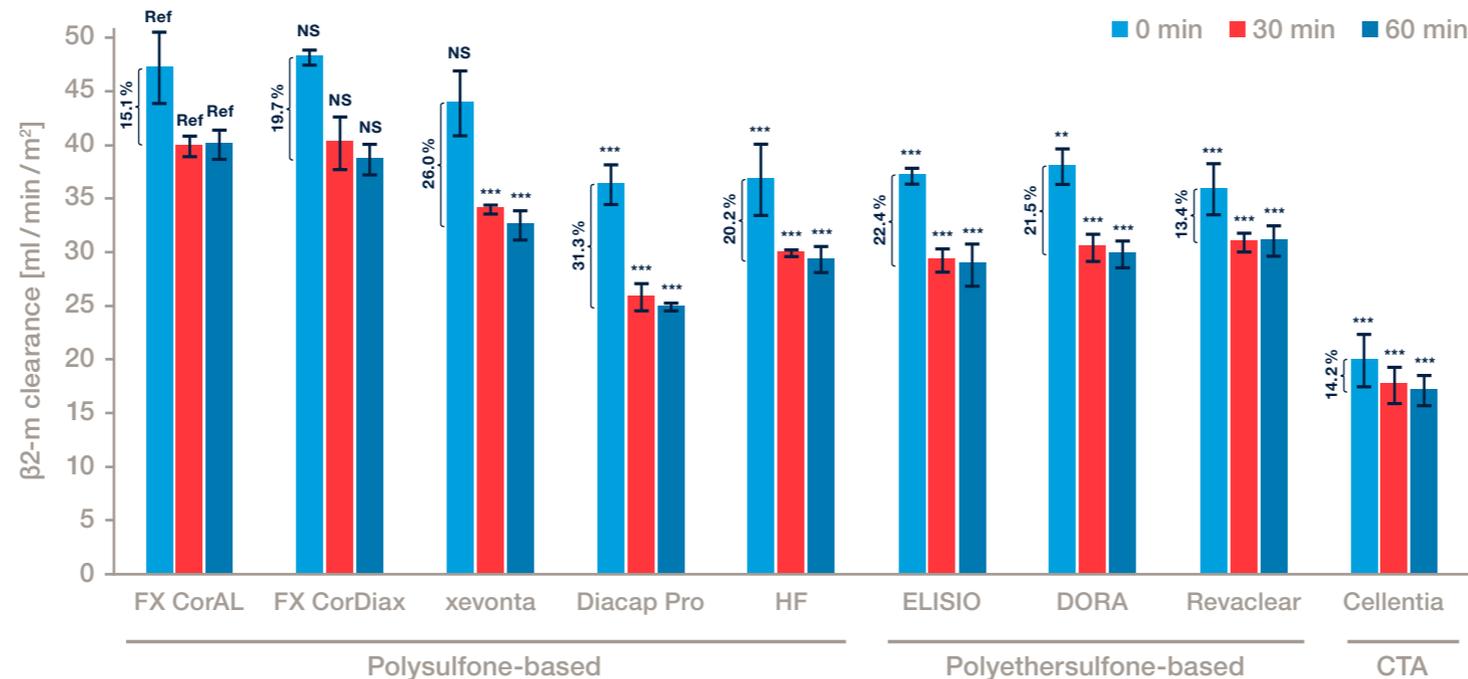


Figure 2. β 2-microglobulin clearance across all tested polysulfone-, polyethersulfone-, and cellulose-based dialyzers at the three time points. Displayed is the mean \pm SD β 2-microglobulin clearance at 0 min (cyan), 30 min (red), and 60 min (blue). The mean relative decrease in β 2-microglobulin clearance between 0 min and 60 min is indicated for each dialyzer. Statistical significance is given with respect to the FX CorAL dialyzer. Ref: reference; NS: not statistically significant; CTA: cellulose triacetate; ** $p < 0.01$, *** $p < 0.001$.

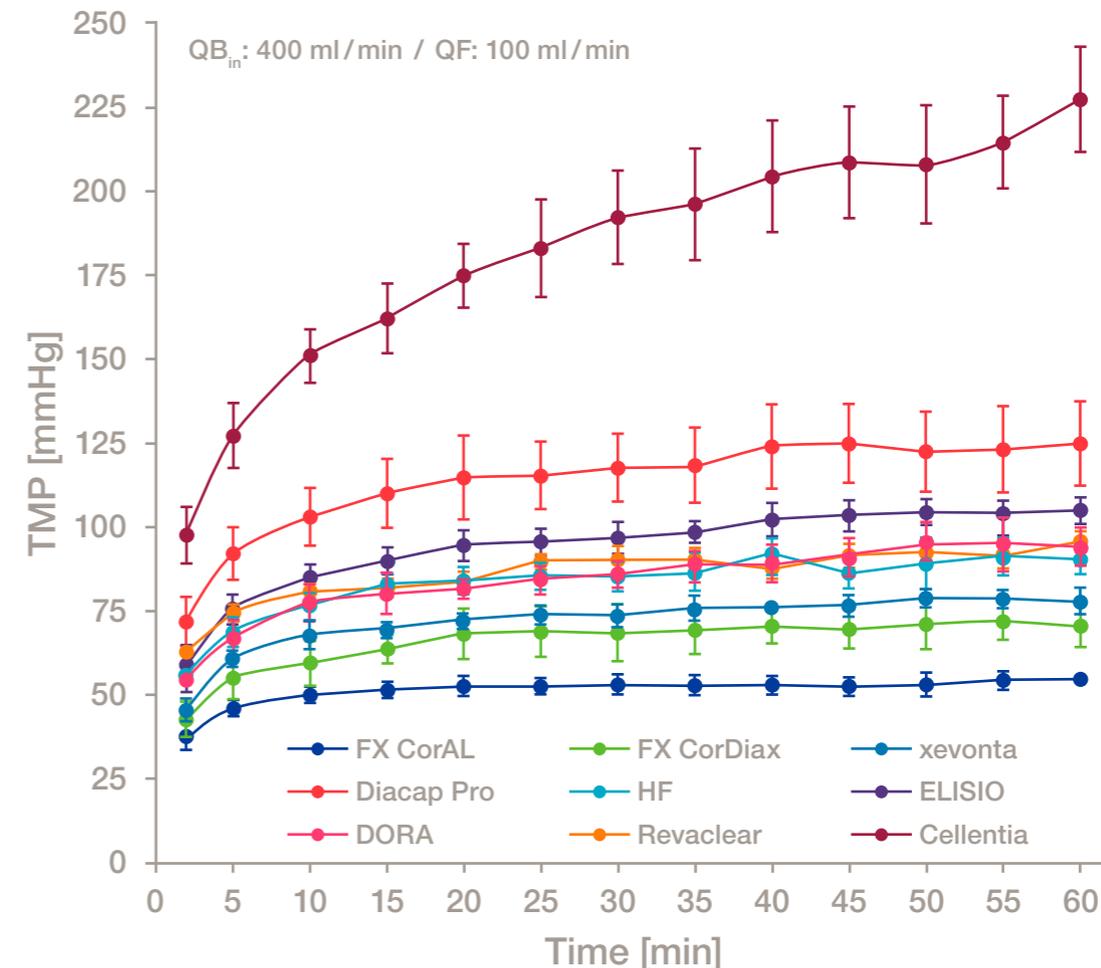
Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Results

Impact of Protein Adsorption on Filtration Performance

- **TMP increased strongly during the first 30 min** (37.2 ± 23.1 mmHg average increase across all dialyzers) and **much slower during the next 30 min** (additional 8.6 ± 10.2 mmHg average increase).
- **FX CorAL** showed the **lowest TMP increase after 30 min** (15.4 ± 2.1 mmHg increase vs. start).
- After an additional 30 min (60 min total), the **TMP increase was lowest for the FX CorAL** dialyzer (17.3 ± 3.0 mmHg increase vs. start) and **statistically lower compared to all other investigated dialyzers, except for the FX CorDiax** dialyzer (27.9 ± 1.3 mmHg; $p = 0.108$).



Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

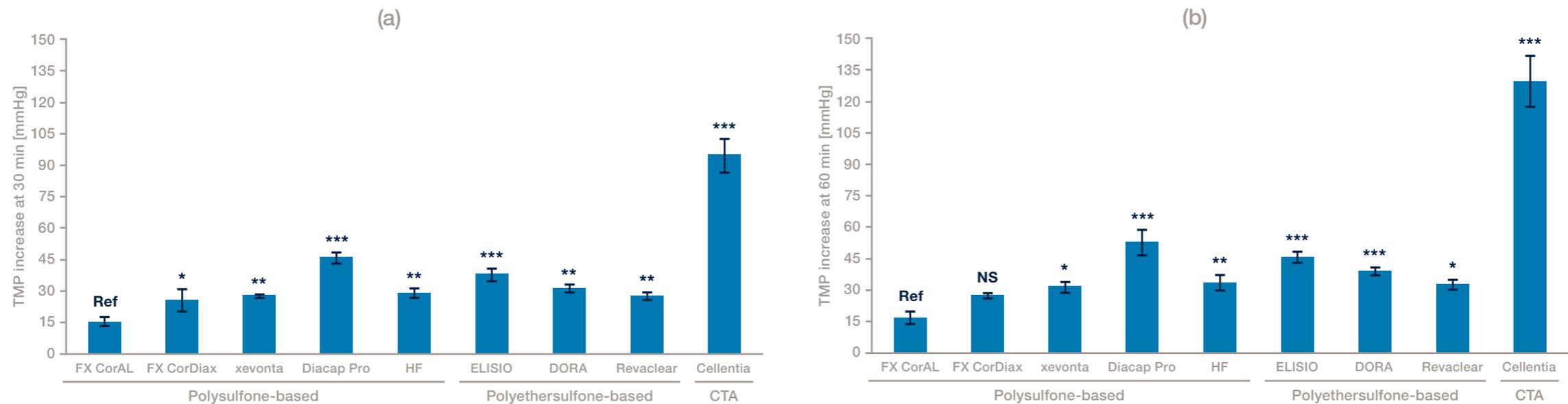


Figure 3. Determination of TMP increase over time: (a) In a recirculation experiment, the TMP was measured continuously at constant flow conditions (inlet flow: 400 mL/min, outlet flow: 300 mL/min, filtrate flow: 100 mL/min) for all tested polysulfone-, polyethersulfone-, and cellulose-based dialyzers. Over 60 min, mean TMP \pm SD is displayed in 5 min intervals; (b) mean \pm SD TMP increase at 30 min (left panel) and 60 min (right panel). Statistical significance is given with respect to the **FX CorAL** dialyzer. Ref: reference; NS: not statistically significant; CTA: cellulose triacetate; * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

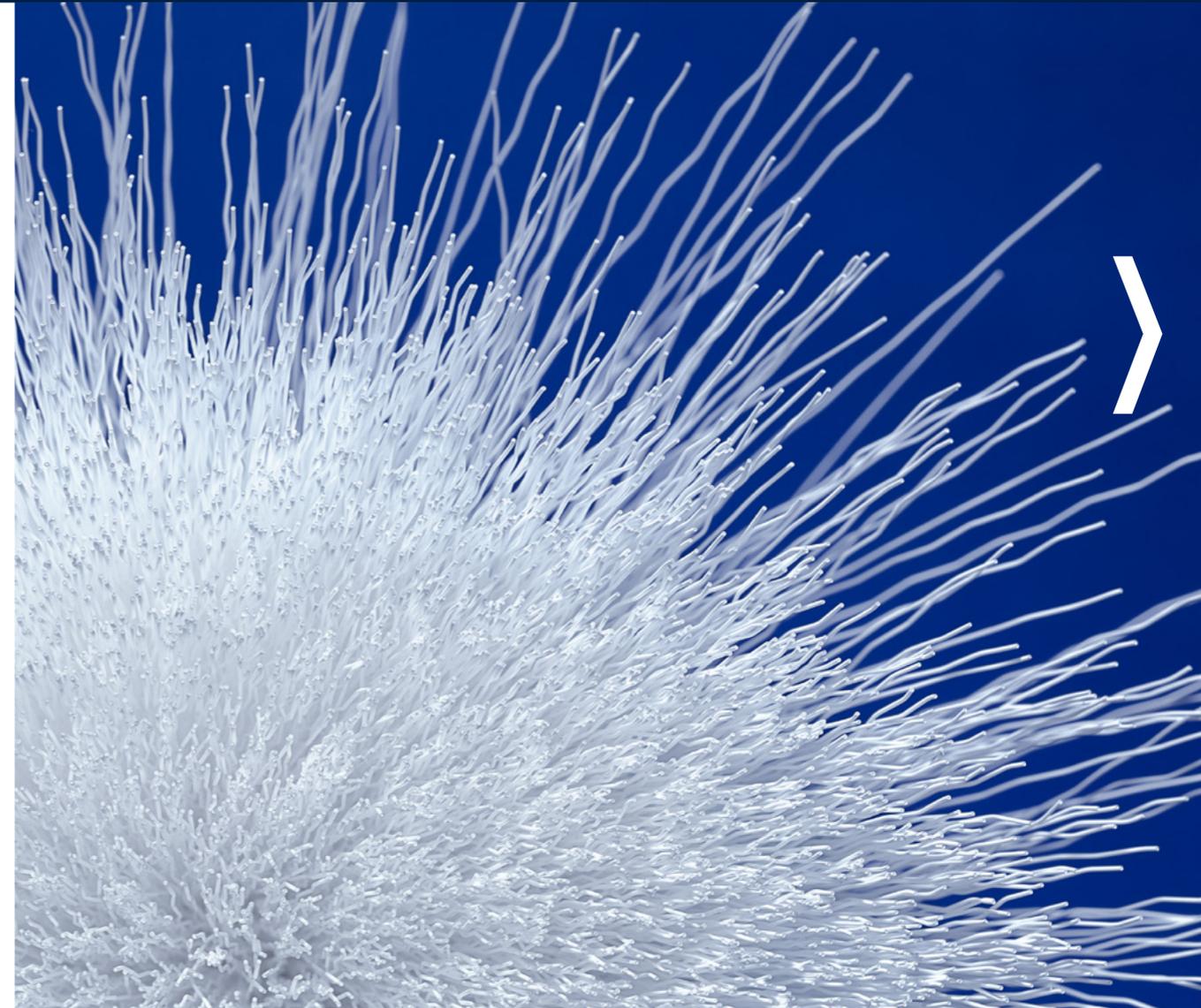
Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Results

Impact of Protein Adsorption on Filtration Performance

- Additionally, filtration characteristics of **FX CorAL**, FX CorDiax, and xevonta, over a standard dialysis time of 4 h were evaluated.
- These experiments over 4 h supported the previous findings that the **reduction in performance mainly occurs in the first 30 min**.
- **FX CorAL** showed the **most stable filtration characteristics over time**, in line with previous data on low secondary membrane formation by its hydrophilic membrane.



Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

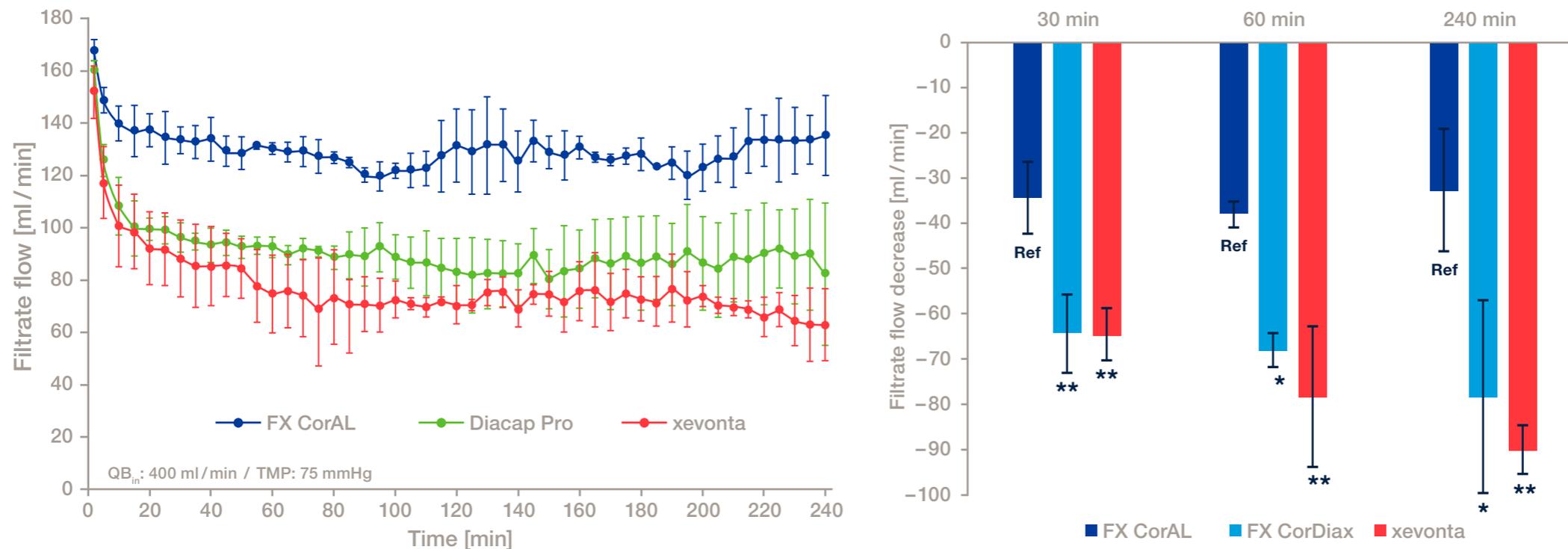


Figure 4. Determination of filtrate flow decrease over time. Left panel: In a recirculation experiment, the filtrate flow at a constant inlet flow (400 mL/min) and TMP (75 mmHg) was measured continuously for the polysulfone-based dialyzers **FX CorAL**, FX CorDiox, and xevonta. Right panel: mean \pm SD decrease in the filtrate flow at 30 min (left), 60 min (middle), and 240 min (right). Statistical significance is given with respect to the **FX CorAL** dialyzer. Ref: reference; * $p < 0.05$, ** $p < 0.01$.

Hydrophilic Modification of Dialysis Membranes Sustains Middle Molecule Removal and Filtration Characteristics

Zawada et al. Membranes (Basel). 2024 Apr 3;14(4):83

Conclusions

- This in vitro study demonstrates that **protein adsorption significantly impacts the performance of dialyzers, particularly in the initial stages of dialysis**, with a marked reduction in the clearance of middle molecules like β 2-microglobulin.
- The data supports the notion that **membrane characteristics**, including **material composition and pore structure**, play a **key role in the stability and efficacy of dialysis treatments**.
- The **FX CorAL** dialyzer, with its **enhanced hydrophilic surface**, showed **superior performance stability**, effectively reducing secondary membrane formation and maintaining high solute clearance.
- These findings underline the importance of optimizing dialyzer design to enhance long-term treatment outcomes for ESRD patients.

Complement activation by dialysis membranes and its association with secondary membrane formation and surface charge

Melchior et al. Artif Organs. 2021;45(7):770-778

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Complement activation by dialysis membranes and its association with secondary membrane formation and surface charge

Melchior et al. Artif Organs. 2021;45(7):770-778

Background

Patients with end-stage renal disease (ESRD) have a high cardiovascular disease (CVD) and mortality risk. The repeated contact of blood with artificial membrane surfaces during dialysis contributes to chronic inflammation in these patients via recurring and sustained activation of the complement system. The proinflammatory anaphylatoxins C3a and C5a as well as the membrane attack complex sC5b-9 are key elements in this process and have been linked to CVD and mortality. To reduce complement activation, the novel **FX CorAL 600** dialyzer is equipped with a modified polysulfone membrane with increased hydrophilicity by α -tocopherol-stabilized polyvinylpyrrolidone (PVP).

Objective

To compare the complement activation of commonly used synthetic and cellulose-based dialyzer membranes ex vivo and link the results to their apparent protein adsorption and surface charge.

Complement activation by dialysis membranes and its association with secondary membrane formation and surface charge

Melchior et al. *Artif Organs*. 2021;45(7):770-778

Methodology

Eight dialyzers containing synthetic or modified cellulose membranes (**FX CorAL 600/80**, FX CorDiax 600/80 [Fresenius Medical Care]; Polyflux 140 H/170 H, THERANOVA [Baxter]; ELISIO-15H/19H, SureFlux-15UX/19UX [Nipro], xevonta Hi 15/20 [B.Braun], FDX-150GW/210GW) were investigated. Complement activation of C3a, C5a, and sC5b-9 was evaluated in an ex vivo recirculation model with human blood from healthy volunteers. Blood was recirculated for 180 min at 200 mL/min. Blood samples for the determination of C3a, C5a, and sC5b-9 were taken before recirculation and at 15, 30, 60, 120 and 180 min during recirculation.

The FX 600 dialyzer (Fresenius Medical Care) was used as reference. Zeta potential was measured as an indicator for differences in the surface charge of the membranes. Albumin sieving coefficients were determined using a four-hour ex vivo recirculation model with human plasma as a surrogate of secondary membrane formation.

Complement activation by dialysis membranes and its association with secondary membrane formation and surface charge

Melchior et al. *Artif Organs*. 2021;45(7):770-778

Results

The **FX CorAL** dialyzer induced the lowest activation of all three complement factors (C3a: 39.4%; C5a: -57.5%; and sC5b-9: -58.9% compared to the reference dialyzer). Application of xevonta Hi 15/20, ELISIO-15H/19H, THERANOVA 400 and SureFlux-15UX/19UX dialyzers led to higher activation of all complement factors, with the cellulose-based SureFlux (C3a: +154.0%) and the FDX (C5a: +335.0%; sC5b-9: +287.9%) dialyzers achieving the highest degree of activation ([Figure 1](#)). Polyflux was comparable with the reference dialyzer for all three complement markers and FX CorDiax was comparable to the reference dialyzer regarding C3a activation, whereas C5a and sC5b-9 levels were increased.

All dialyzers had negatively charged surfaces. With a nearest-to-neutral zeta potential at 2.38 mV, the membrane

of **FX CorAL** was significantly less negative than those of FX CorDiax (-5.56 mV), SureFlux (-6.28 mV), ELISIO (-7.12 mV), Polyflux (-7.15 mV), xevonta (-7.30 mV), THERANOVA (-9.39 mV), and FDX (-25.74 mV) ($p < 0.001$ for all comparisons). Furthermore, the **FX CorAL** had the lowest decrease in the albumin sieving coefficient over time. The drop was significantly lower compared to the dialyzers xevonta, FDX, THERANOVA and SureFlux ($p < 0.001$ for all comparisons), whereas the differences with respect to ELISIO ($p = 1.0$), Polyflux ($p = 0.7$) and FX CorDiax ($p = 0.3$) were not statistically significant ([Figure 2](#)).

With the synthetic dialyzers a strong correlation between complement activation and changes in the albumin sieving coefficient was observed over time.

Complement activation by dialysis membranes and its association with secondary membrane formation and surface charge

Melchior et al. Artif Organs. 2021;45(7):770-778

Conclusion

Featuring membrane surface modification with α -tocopherol-stabilized PVP, the novel **FX CorAL** dialyzer may reduce complement activation in comparison to other commonly used dialyzers for the treatment of hemodialysis patients. The reduced complement activation was associated with near-neutral zeta potential and lower albumin sieving coefficient decrease over time, and may indicate a reduced secondary membrane formation. Whether these observations will result in a lower inflammatory burden in hemodialysis patients has yet to be investigated in clinical studies.



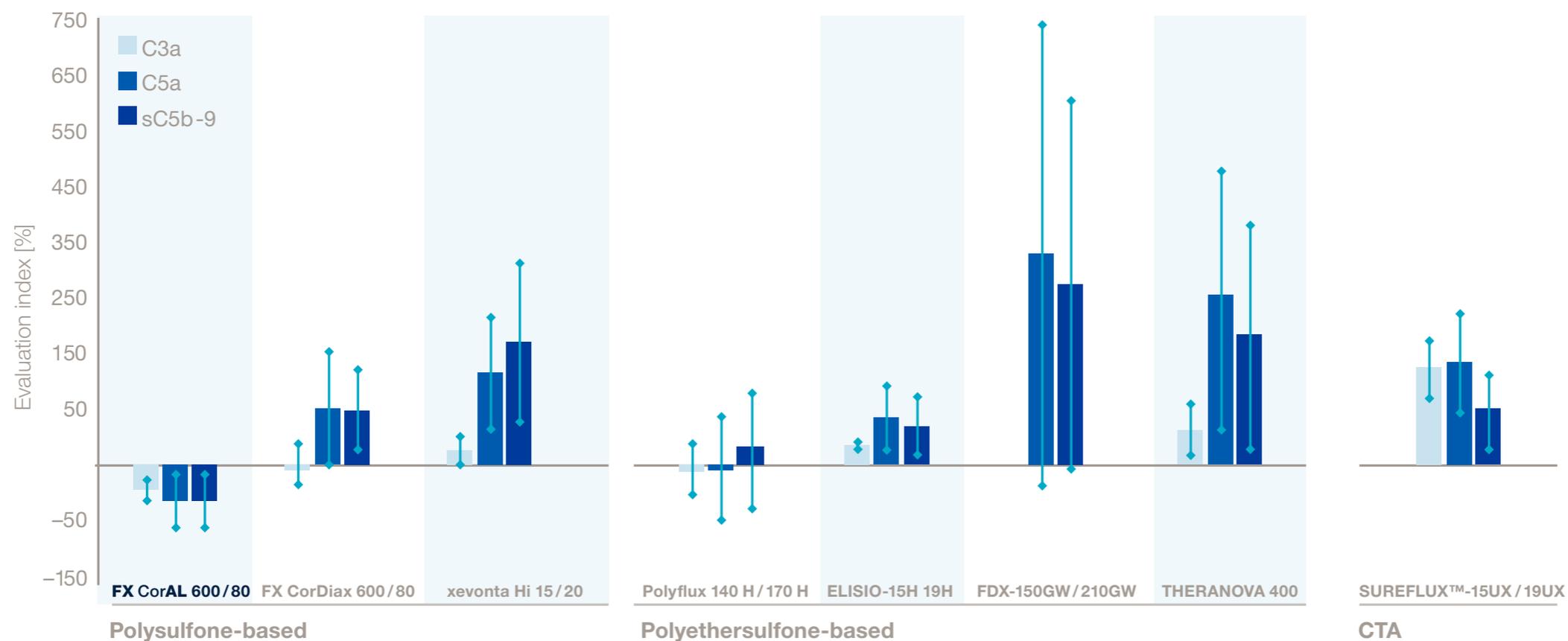


Figure 1: Complement activation by the investigated dialyzers. Activation of C3a, C5a and sC5b-9 is presented with respect to the reference dialyzer FX 600. Displayed are means and confidence intervals of six measurements per dialyzer.

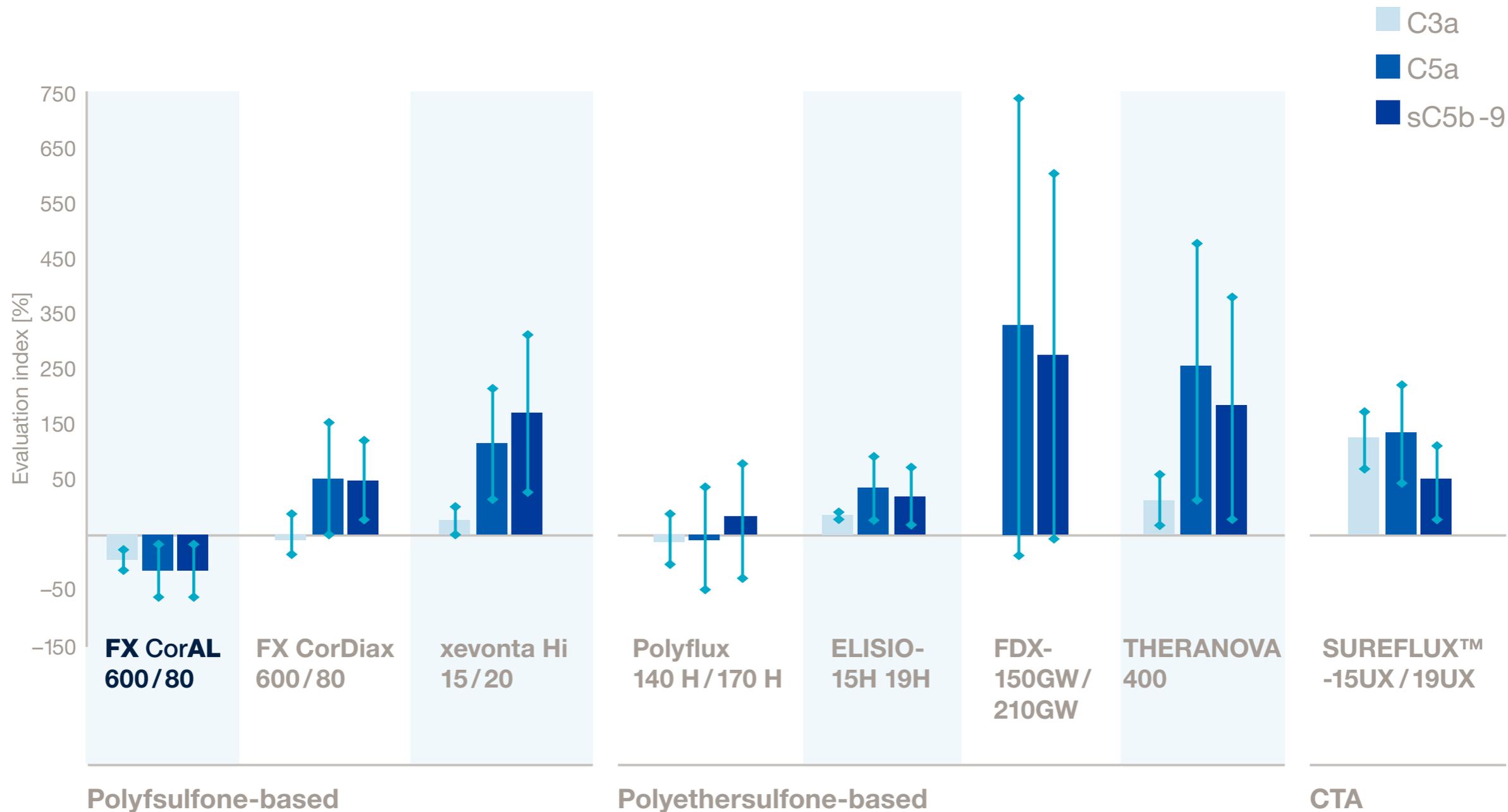


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Complement activation by dialysis membranes and its association with secondary membrane formation and surface charge

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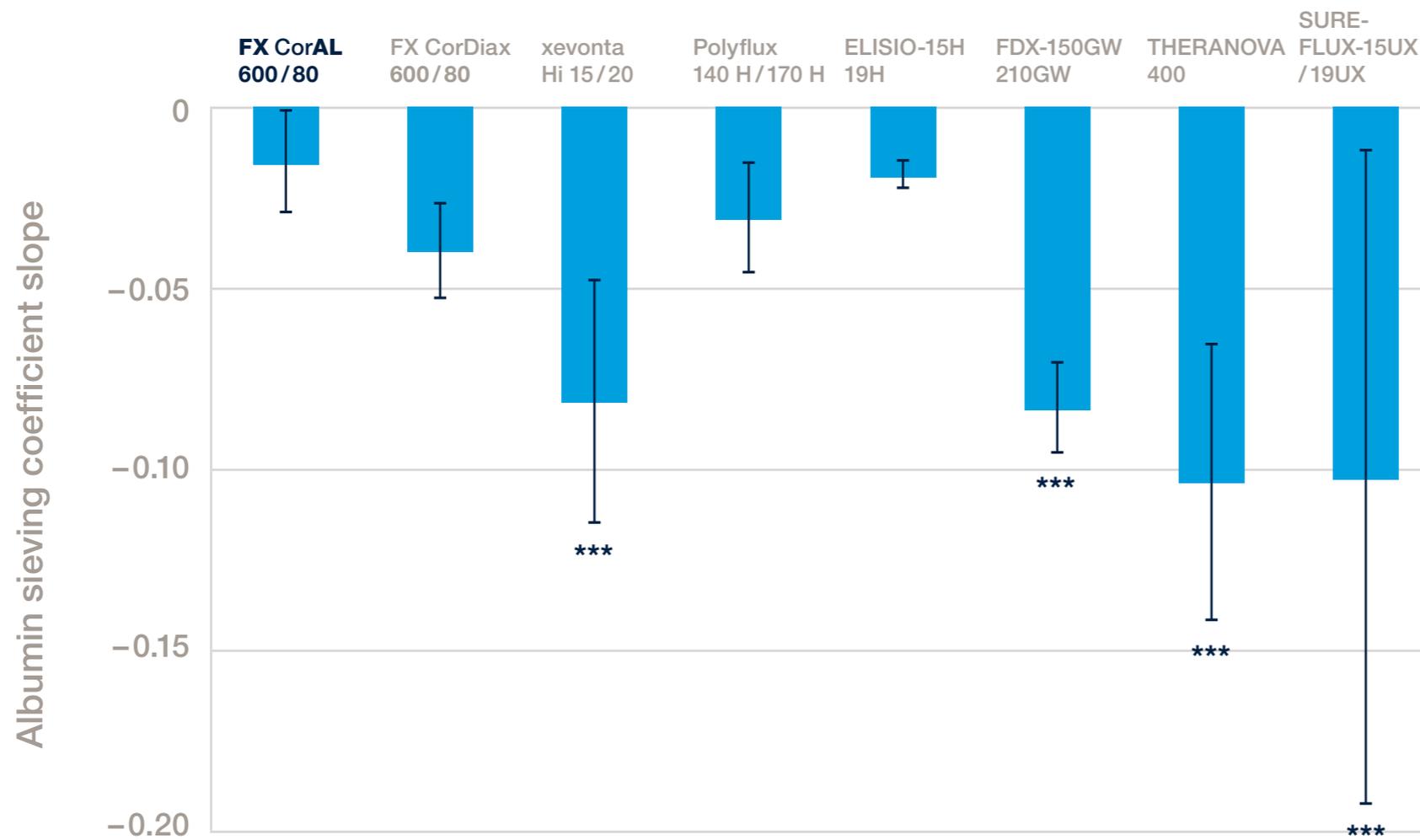


Figure 2: Decreases in albumin sieving over time by the investigated dialyzers. Albumin sieving is used as a surrogate for loss of performance over time. Displayed are means and confidence intervals of six measurements per dialyzer.

Polyvinylpyrrolidone in hemodialysis membranes: Impact on platelet loss during hemodialysis

Zawada et al. Hemodialysis International. 2021;25:498–506

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Polyvinylpyrrolidone in hemodialysis membranes: Impact on platelet loss during hemodialysis

Zawada et al. Hemodialysis International. 2021;25:498–506

Background

Polyvinylpyrrolidone (PVP) is commonly used as a hydrophilic agent for synthetic dialyzer membranes to reduce secondary membrane development and enhance hemocompatibility. While good coverage of PVP on the blood-side surface reduces undesired platelet activation and platelet waste during hemodialysis treatment, elution of various amounts of PVP into the filtrate has been observed, depending on the applied sterilization method. To avoid adverse events potentially associated with PVP elution into the blood and to preserve performance and hemocompatibility, the development of novel dialysis membranes aims at good PVP coverage on the blood-side surface and low PVP elution during treatment. To this end, a low concentration of α -tocopherol (Vitamin E) is used to stabilize PVP on the blood-side membrane surface of the novel **FX CorAL** dialyzer.

Objective

To investigate the PVP content and its elution of six commercially available PVP-containing dialyzers and to link the results to the level of platelet loss as marker of biocompatibility.

Polyvinylpyrrolidone in hemodialysis membranes: Impact on platelet loss during hemodialysis

Zawada et al. Hemodialysis International. 2021;25:498–506

Methodology

Six dialyzers from four companies were investigated: FX CorDiax 600 and **FX CorAL 600** by Fresenius Medical Care (sterilized by INLINE steam), Polyflux 170H and THERANOVA 400 by Baxter (autoclave steam sterilized), ELISIO-17H by Nipro and xevonta Hi 15 by B. Braun (gamma sterilized).

To determine the relative amount of PVP on the blood-side surface of each dialyzer membrane, X-ray photoelectron spectroscopy (XPS) measurements were performed. To measure PVP elution, the dialyzers were recirculated with 1 L water (300 mL / m² dialyzer surface, 37°C) for 5 h.

Afterwards, the amount of eluted PVP was measured spectrophotometrically at 470 nm. Platelet loss was determined using an ex vivo circulation system with fresh human whole blood from six different donors. Within 30 min after blood collection, recirculation experiments were conducted, which consisted of a parallel run (3 h at 200 mL / min) of test and reference dialyzer (FX 600 by Fresenius Medical Care) with blood from the same donor. Platelet counts were determined from blood samples taken before and at 15, 30, 60, 120 and 180 min during recirculation.

Polyvinylpyrrolidone in hemodialysis membranes: Impact on platelet loss during hemodialysis

Zawada et al. Hemodialysis International. 2021;25:498–506

Results

The polysulfone-based **FX CorAL** dialyzer had the highest PVP content on the blood-side surface (26.3%), followed by xevonta (24.7%), ELISIO (24.4%), FX CorDiax (23.0%), Polyflux (18.3%) and THERANOVA (15.6%). PVP elution was lowest for the INLINE steam sterilized **FX CorAL** and FX CorDiax with amounts in the filtrate below the quantification limit (<0.5 mg / 1.6 m² dialyzer). Significantly higher amounts of eluted PVP ($p < 0.001$) were found for the autoclave steam sterilized THERANOVA (9.1 mg / 1.6 m² dialyzer), Polyflux (9.0 mg / 1.6 m² dialyzer), and for the gamma-radiation sterilized xevonta (3.2 mg / 1.6 m² dialyzer), and ELISIO dialyzers (2.1 mg / 1.6 m² dialyzer).

Compared to the reference dialyzer FX 600, the **FX CorAL** dialyzer showed by far the most profound reduction of platelet loss with -225.2% , followed by ELISIO (-52.5%). All other tested dialyzers led to an increase in platelet loss with highest values for the xevonta dialyzer ($+164.4\%$), followed by THERANOVA ($+95.5\%$), FX CorDiax ($+14.2\%$) and Polyflux ($+5.0\%$). The platelet loss observed with **FX CorAL** was significantly lower compared to THERANOVA ($p = 0.016$) as well as xevonta ($p = 0.005$) (Figure 1).

Polyvinylpyrrolidone in hemodialysis membranes: Impact on platelet loss during hemodialysis

Zawada et al. Hemodialysis International. 2021;25:498–506

Conclusion

The six investigated dialyzers differed in the PVP content of their inner membrane surfaces, whereby **FX CorAL** exhibited the highest PVP content. PVP elution was linked to the method of sterilization, with the INLINE steam sterilized **FX CorAL** and FX CorDiax dialyzers displaying the lowest PVP elution, and autoclave sterilized dialyzers having the highest amounts of eluted PVP.

A high PVP content and a low PVP elution were associated with a lower platelet loss. This confirms previous studies showing that an increased PVP content on the inner surface of the membrane increases the biocompatibility profile of the dialysis membrane.

Polyvinylpyrrolidone in hemodialysis membranes: Impact on platelet loss during hemodialysis

Zawada et al. Hemodialysis International. 2021;25:498–506

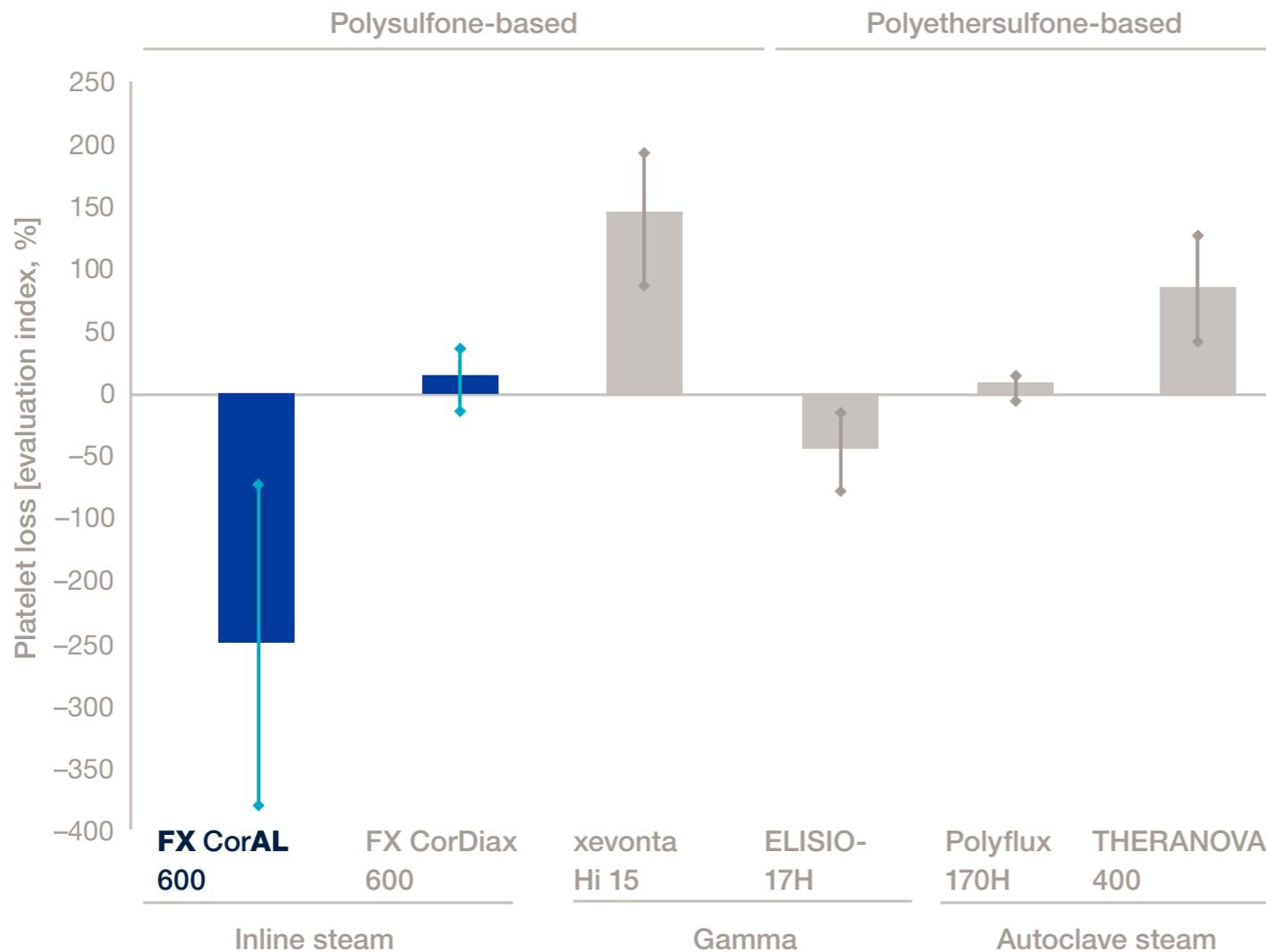


Figure 1: Platelet loss by the investigated polysulfone- and polyethersulfone-based dialyzers. Platelet loss (evaluation index) is presented with respect to the reference dialyzer (FX 600). The means \pm SD of six measurements per dialyzer present the area under the curve from 0–60 min. The three different sterilization methods, INLINE steam, gamma, and autoclave steam, are indicated.

Graph adapted from Zawada et al., 2021, p. 52

Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzer

Zawada et al. Artif Organs. 2022 Jul;46(7):1318-1327

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Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzers

Zawada et al. Artif Organs. 2022 Jul;46(7):1318-1327

Background

Patients with end-stage renal disease (ESRD) have limited therapeutic options and renal replacement therapy via hemodialysis is one of them. Dialyzer membranes have been improved in recent years to allow removal of medium-sized molecules in addition to small solutes. However, protein adhesion on the blood-side surface of the membrane during treatment leads to formation of a so-called secondary membrane, which diminishes the toxin removal capacity over time. The novel **FX CorAL** dialyzer (Fresenius Medical Care) is equipped with a membrane improved by hydrophilic modifications with α -tocopherol-stabilized polyvinylpyrrolidone (PVP) to reduce protein adsorption, the so-called secondary membrane development.

Objective

To assess the time-resolving molecular weight retention changes among synthetic high-flux dialyzers and to compare the results with data from the randomized controlled comPERFORM (Comparative Clinical Performance of Dialyzers Applied During High Volume Online Haemodiafiltration) study.

Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzers

Zawada et al. Artif Organs. 2022 Jul;46(7):1318-1327

Methodology

Three dialyzers were investigated, which were also used in the comPERFORM study (NCT04102280): **FX CorAL 600** by Fresenius Medical Care, ELISIO- 17H by Nipro and xevonta Hi 15 by B. Braun. To determine sieving coefficients of β 2-microglobulin, myoglobin and albumin over time, recirculation experiments were performed with human plasma for 4 hours. Plasma samples were taken pre-dialyzer, post-dialyzer and on the filtrate side at 2, 5, 10, 15, 30, 45, 60, 120, 180 and 240 min.

As a surrogate marker for protein fouling the transmembrane pressure (TMP) was assessed. Molecular weight retention (MWR) curves were generated based on the sieving coefficients and the effective pore radius calculated depending on the MWR curves. The predicted albumin loss over four hours was determined and compared with clinical data.

Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzers

Zawada et al. Artif Organs. 2022 Jul;46(7):1318-1327

Results

The sieving coefficients of all three proteins decreased over time for all investigated dialyzers with a mean relative decrease in 8.0% (β 2-microglobulin, 120 min), 56.6% (myoglobin, 240 min), and 94.1% (albumin, 240 min), respectively. The decrease in the sieving coefficients was lower for **FX CorAL** (7.3%, 52.6% and 91.1%) and ELISIO (7.7%, 51.0% and 93.8%) than for xevonta (9.0%, 66.2% and 97.4%). The TMP increased over time for all three dialyzers. The strongest increase occurred in the first 30 min and was lowest for **FX CorAL** (8.8%), followed by ELISIO (11.6%) and xevonta (14.4%).

The molecular weight retention curves changed over time for all three dialyzers toward lower molecular weight. At 120 min the shift was most pronounced for the xevonta dialyzer (change in Stokes radius of 0.50 nm), followed by ELISIO (0.29 nm) and lowest for **FX CorAL** (0.23 nm). At the later time points, between 120 min and 240 min, the MWR curves did not significantly shift further. The slope of the MWR curves differed between the dialyzers, with the **FX CorAL** having the highest MWR curve slope and thus best mimicking the glomerular sieving characteristics (Fig. 1 a).

Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzers

Zawada et al. Artif Organs. 2022 Jul;46(7):1318-1327

Results

Although the highest effective pore radius was measured for the xevonta dialyzer at the beginning of the experiment, it decreased the most for this dialyzer (decrease of 0.50 nm after 120 min), followed by the ELISIO (0.29 nm) and the **FX CorAL** with the smallest reduction of 0.23 nm. Generally, the **FX CorAL** had the most uniform pore size distribution (0.70 nm at 2 min and 0.86 nm at 120 min) while the ELISIO and xevonta dialyzers showed a larger effective pore size distribution (Fig. 1 b).

The predicted albumin loss was strongest in the first 30 min of the experimental period. After four hours, the highest loss was found for the xevonta dialyzer (609.8 ± 105.9 mg; $p=0.003$), whereas the predicted albumin loss was comparable between ELISIO (283.6 ± 6.3 mg; $p=0.810$) and **FX CorAL** (313.3 ± 41.8 mg).

Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzers

Zawada et al. Artif Organs. 2022 Jul;46(7):1318-1327

Conclusion

The study provides insights into the changes in performance of the three dialyzers **FX CorAL**, ELISIO and xevonta after contact of plasma proteins with the membrane surface.

The novel **FX CorAL** dialyzer was found to have the lowest decrease in performance, which corroborates data from the randomized controlled trial comPERFORM.

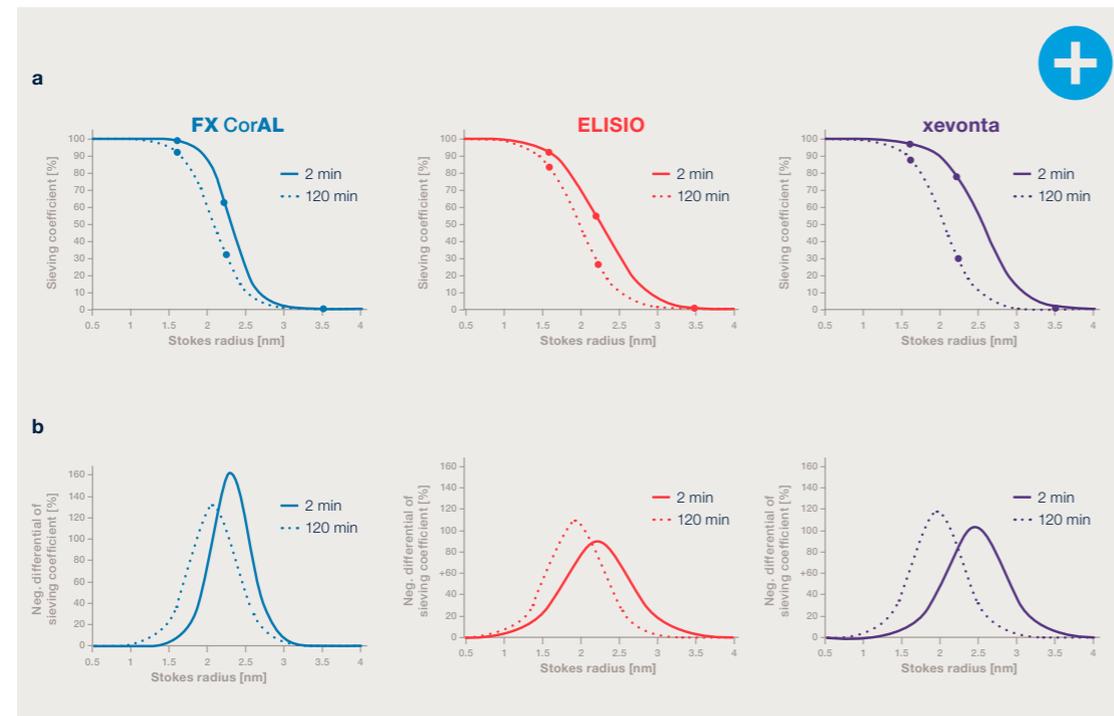


Figure 1:

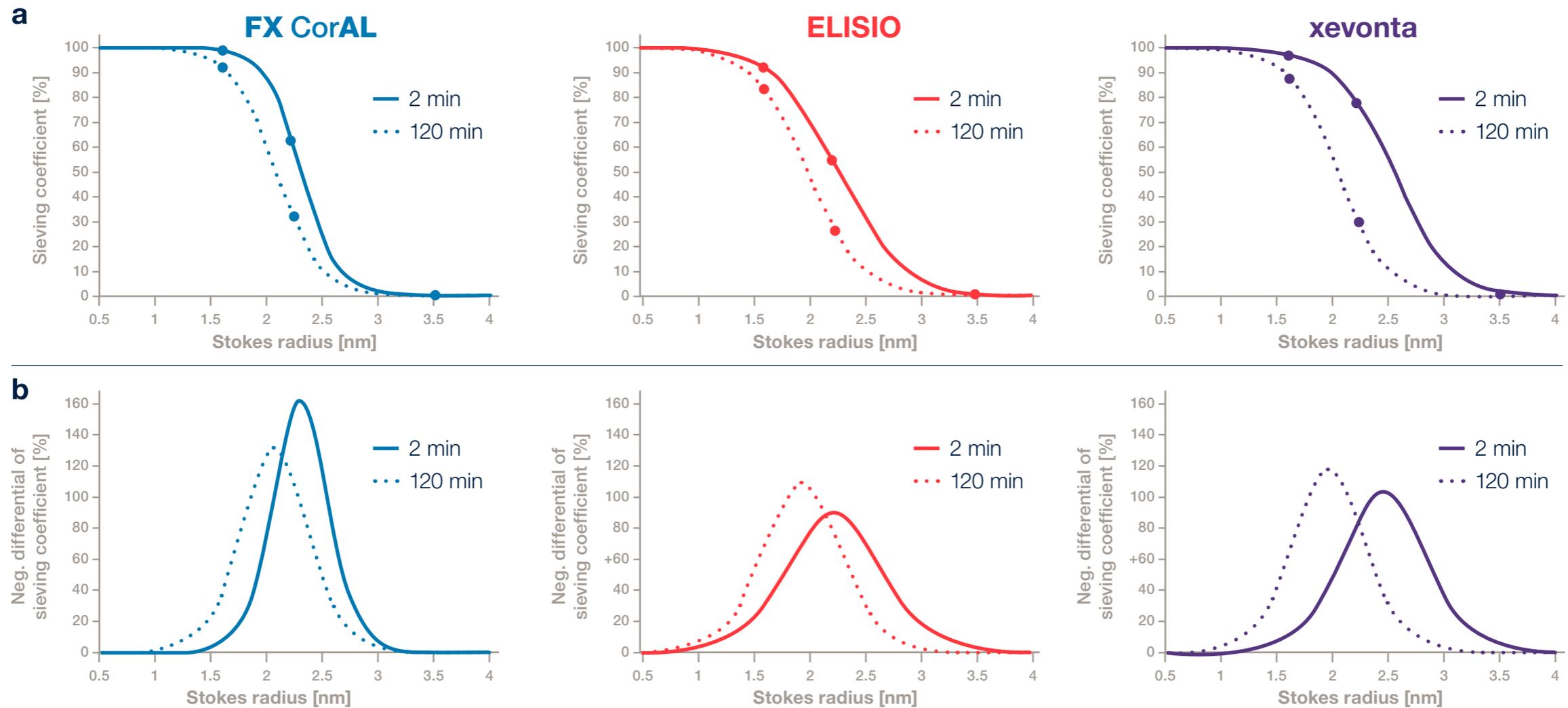
a Molecular weight retention curves over time based on the sieving coefficients for β 2-microglobulin, myoglobin and albumin for the different time points (2 min: solid line, 120 min: dotted line) for the **FX CorAL** (blue), **ELISIO** (red) and **xevonta** (purple). The dots indicate the respective means of the three independent measurements.

b Effective pore radii over time. The negative differential of the sieving coefficient was calculated as a surrogate for the effective pore radius distribution for the different time points (2 min: solid line, 120 min: dotted line) for the **FX CorAL**, **ELISIO** and **xevonta**.



Time-resolving characterization of molecular weight retention changes among three synthetic high-flux dialyzers

Zawada et al. *Artif Organs*. 2022 Jul;46(7):1318-1327



Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

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Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

Background

In patients with end-stage renal disease (ESRD) receiving extracorporeal treatments, a dialyzer replaces the blood-filtering function of the malfunctioning kidneys by eliminating uremic toxins, such as β 2-microglobulin, urea, uric acid, or creatinine, while preventing loss of essential proteins, such as albumin. Factors influencing the performance of a dialyzer include membrane composition, structure, morphology, and adsorptive properties. To avoid negative consequences for the patient, hemocompatibility is an important feature of a dialyzer, because perpetuated contact of blood with artificial surfaces triggers complement activation, coagulation and immune cell activation.

Objective

To provide insight into the importance of dialyzer performance and hemocompatibility for the treatment of ESRD patients and into the improvement of dialyzer membranes by hydrophilic modifications.

Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

Importance of dialyzer performance and hemocompatibility

Elimination of toxins from the patients' blood is mostly dependent on the pore size of the membrane. To avoid accumulation of middle-sized uremic toxins, which is associated with increased inflammation, cardiovascular risk and mortality, pore sizes have been increased in recent years to allow the removal of these larger molecules. This, however, increased the risk of losing larger essential proteins, such as albumin, leading to malnutrition and increased mortality. Therefore, in addition to its clearance of middle-sized toxins, the performance of a dialyzer should be described by its overall sieving properties including the permeability cut-off for larger molecules.

Recent studies indicated a causal role of the complement system in inducing cardiovascular events. Triggers include activation of the complement and coagulation system as well as an increase in markers for inflammation, oxidative stress and tissue damage after the contact of blood with non-body surfaces. To achieve a good hemocompatibility profile, current dialyzers use synthetic membranes with polysulfone (PS) or polyethersulfone (PES) polymers, which are associated with less transient complement activation and drops in leukocyte counts than cellulose-based membranes.

Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

Impact of membrane fouling

Protein adhesion on the blood-side surface of the membrane during treatment leads to formation of a so-called secondary membrane that diminishes the toxin removal capacity over time. In addition, the hemocompatibility profile of the dialyzer is influenced by the protein adsorption to the membrane surface, which provokes changes in the protein structures

and leads to protein activation. This may trigger the activation of various pathways, such as immune cell, complement or coagulation system. Reduction of protein adsorption to the membrane during hemodialysis is the key to improving the dialyzers' performance and hemocompatibility profile.

Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

Hydrophilic modifications

Polyvinylpyrrolidone (PVP) is commonly used as hydrophilic agent for synthetic polysulfone- or polyethersulfone-based membranes to diminish secondary membrane development. With higher PVP content, stronger water adsorption leading to reduced protein adsorption could be observed (Figure 1). Consequently, this was associated with increased blood coagulation time, reduced platelet adhesion and lower complement activation. Two randomized controlled trials with the comPERFORM study (NCT04102280) and the eMPORA II study (NCT03611218) demonstrated that the reduced secondary membrane formation of the more hydrophilic membrane used in the novel **FX CorAL** dialyzer was associated with efficient removal of small and medium molecules and a favorable hemocompatibility profile.

PVP can be eluted from the membrane during dialysis, however an association between PVP elution and adverse reactions in patients has not been determined in any studies so far. Nevertheless, to maintain the hydrophilic modification during sterilization and prevent PVP leaching into the patient's circulation, the method of choice is proposed as INLINE steam sterilization, in which the membranes are continuously rinsed with steam and sterile water. Additionally, membranes with the anti-oxidant α -tocopherol to stabilize the PVP are to be recommended.

Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

Conclusion

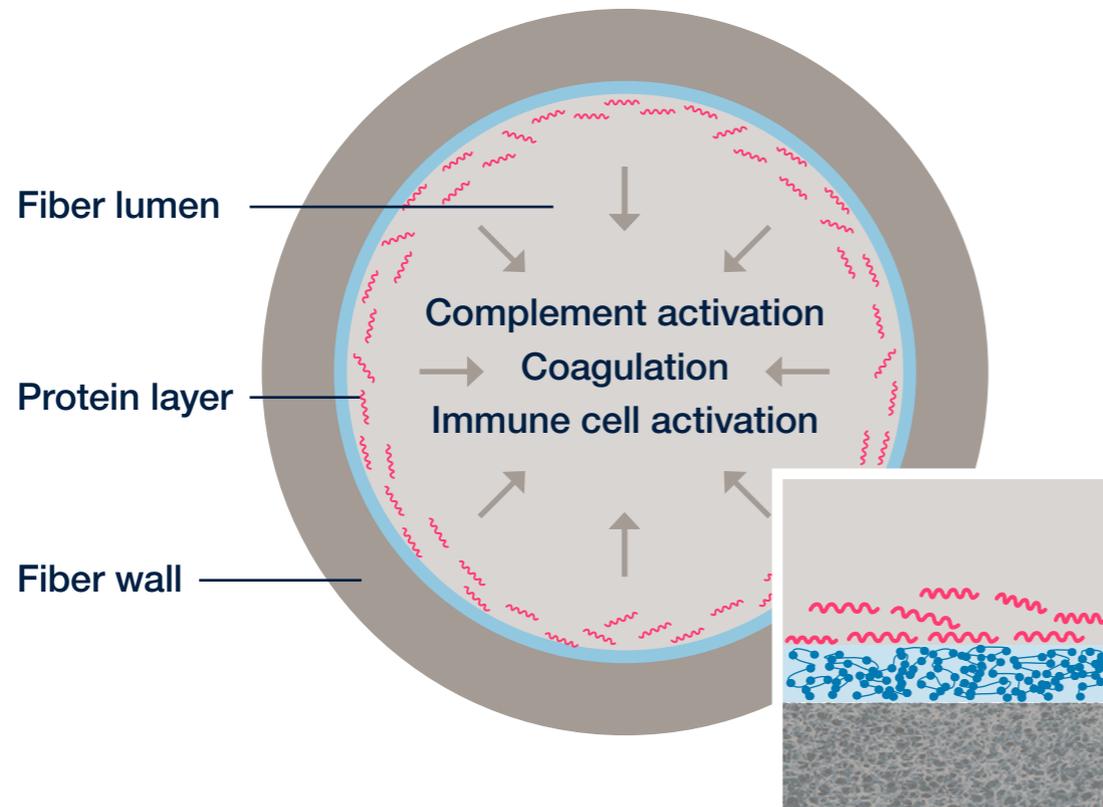
Hydrophilic modifications of synthetic dialysis membranes are very effective in improving the performance and hemocompatibility of a dialyzer. Further research is needed to evaluate the long-term effects of hydrophilic membrane modifications on the reduction of inflammatory and cardiovascular consequences for dialysis patients.

Figure 1 (next slide): Schematic illustration of complement activation, coagulation and immune cell activation by a membrane with strong protein adsorption compared to a hydrophilic membrane with lower protein adsorption. An increase in hydrophilicity can be achieved by increasing the content of the hydrophilic agent polyvinylpyrrolidone (PVP) on the blood-side surface of the membrane.

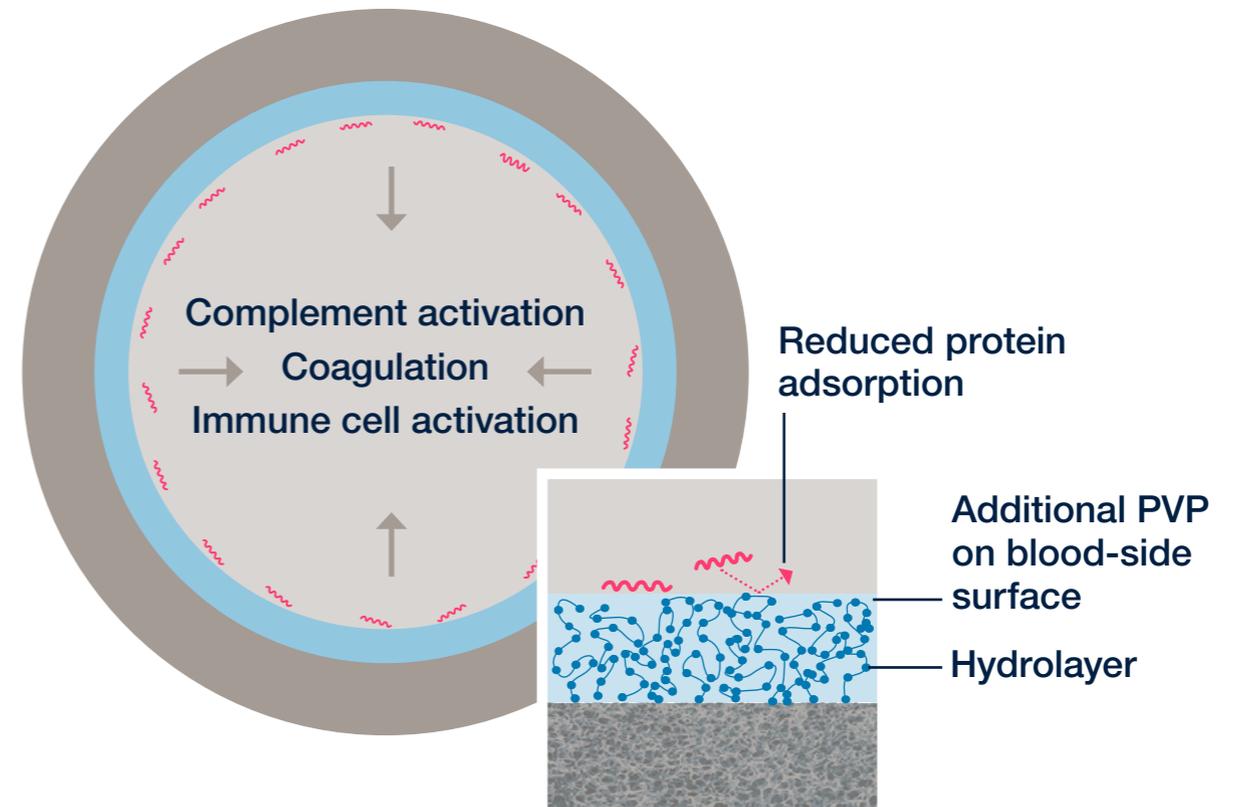
Impact of hydrophilic modification of synthetic dialysis membranes on hemocompatibility and performance

Zawada et al. Membranes 2022, 12, 932

Membrane with strong protein adsorption



Hydrophilic membrane with lower protein adsorption



Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387
at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

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Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387 at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

Background

In order to reduce interactions with plasma proteins and platelets during dialysis, the hydrophilic properties of polysulfone hemodialyzer membranes are increased with polyvinylpyrrolidone (PVP). To stabilize the PVP on the blood-side surface in the polysulfone dialysis membrane, a modified spinning technique has been established in the novel **FX CorAL 600** dialyzer.

Objective

To investigate the performance (medium-sized molecular clearance and removal rate) of **FX CorAL 600** in comparison to the established dialyzers FX 600 and FX CorDiax 600 from the same manufacturer. In addition, hemocompatibility and safety of the dialyzers were explored.

Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387 at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

Methodology

eMPORA I (Safety and clinical performance of a dialyzer with a Modified POLysulfone membRAnE) was a multicenter, prospective, randomized, crossover study (NCT03315624). Adult patients on online hemodiafiltration (HDF) were randomized to treatment applied as online HDF in post-dilution mode with the dialyzers **FX CorAL 600**, FX 600, and FX CorDiax 600 (all Fresenius Medical Care, Bad Homburg, Germany) for one week each. Performance was determined

as removal rate and clearance of β 2-microglobulin, myoglobin, urea, creatinine and phosphate. Blood samples were taken at the midweek session before the start and at the end to analyze removal rate and at 60 min to determine clearance. To assess hemocompatibility, levels of factors of complement activation (C3a, C5a, sC5b-9) were assessed during dialysis. Furthermore, safety was evaluated.

Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387 at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

Results

In total, 49 patients

(mean \pm SD age 66.3 ± 13.6 years, 76% male)

were included in the study.

Treatments were performed in post-dilution mode with a mean blood flow of > 300 mL/min and a substitution volume of > 19 L.



Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387 at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

Performance

The study demonstrated superiority of the **FX CorAL 600** dialyzer versus FX 600 with respect to a higher β 2-microglobulin removal rate (74.4% versus 70.4%, $p=0.0006$) (Figure 1) as well as an improved clearance of β 2-microglobulin and myoglobin. In terms of β 2-microglobulin, the removal rate of **FX CorAL 600** was higher, yet did not reach statistical significance compared to the FX CorDiax 600 (74.4% versus 73.1%). Clearance of β 2-microglobulin and myoglobin was comparable between **FX CorAL 600** and FX CorDiax 600. Performance with regard to small molecules was similar for all dialyzers.

Hemocompatibility

FX CorAL 600 showed a significantly lower increase of complement factors C5a and sC5b-9 than FX 600 at 15 min after treatment start ($p=0.007$ for C5a; $p=0.009$ for sC5b-9). The increase of C3a at 15 min and sC5b-9 at 60 min was similar between all dialyzers. Furthermore, no difference was discerned in the increase of C5a at 15 min between **FX CorAL 600** and FX CorDiax 600. The area-under-the-curve for the course of sC5b-9 with **FX CorAL 600** was significantly lower than with FX 600 ($p=0.044$) and comparable to FX CorDiax 600 ($p=0.092$). Leukocytes slightly decreased within the first 15 min and recovered afterwards in a comparable course with all dialyzers.

Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387 at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

Safety

All three dialyzers did not differ with respect to adverse events.

Conclusion

All three dialyzers showed good performance, with higher removal rates of medium-sized molecules for the new dialyzer **FX CorAL 600** compared to the FX 600. Improved hemocompatibility of the **FX CorAL 600** was indicated by significantly lower complement activation of C5a and of sC5b-9 compared to FX 600. Overall, the novel **FX CorAL 600** is a highly performing dialyzer that was associated with a low frequency of adverse events.

Clinical performance, hemocompatibility and safety of a new dialyzer with a modified polysulfone membrane

Kempkes-Koch et al. Oral presentation MO387 at the 58th ERA-EDTA Congress, Virtual, June 5-8, 2021

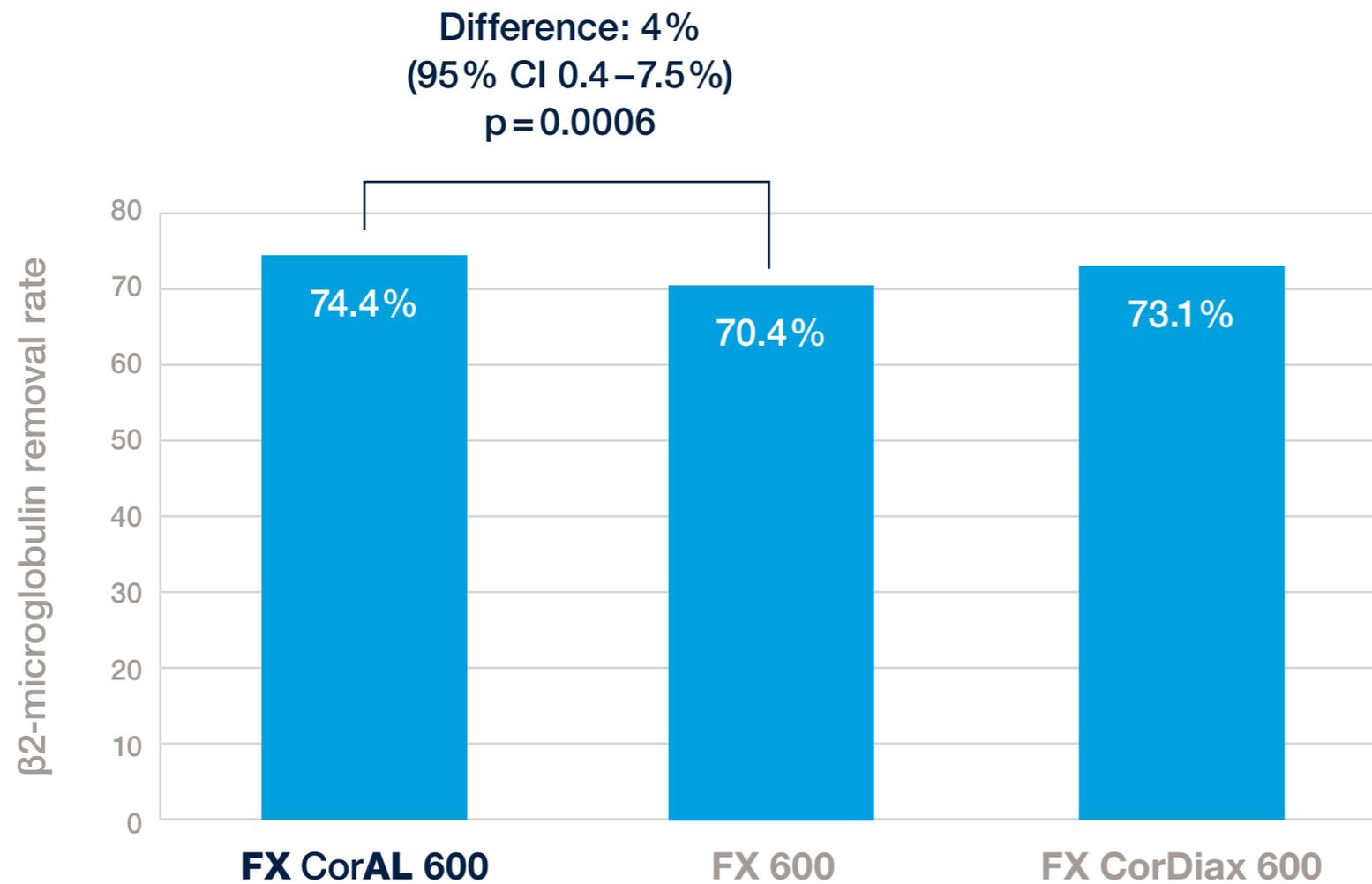


Figure 1: Removal rate of β 2-microglobulin by investigated dialyzer

Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

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Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Background

High-flux dialyzers are designed to mimic the elimination characteristics of the kidney. In addition to a sharp molecular weight cut-off to prevent excessive albumin loss, excellent hemocompatibility is a prerequisite to minimize intradialytic humoral and cellular stimulation. Cell reactions and release of humoral factors may be triggered upon contact of blood with dialysis membranes, in particular with those based on cellulose. The release of humoral factors may contribute to undesired long-term effects on patient outcomes, for instance, cardiovascular events and increased infection risk. The novel **FX CorAL 600** dialyzer was developed, to improve hemocompatibility, with a modified polysulfone / polyvinylpyrrolidone (PS / PVP) membrane surface. Small amounts of α -tocopherol were added to stabilize the blood-side membrane surface against PVP oxidation and elution.

Objective

To determine performance (removal rate and clearance of β 2-microglobulin and other uremic retention solutes) and hemocompatibility of **FX CorAL 600** in comparison with two commercially available dialyzers.

Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Methodology

eMPORA II (Comparative Safety and Clinical Performance of Dialyzers Applied During Post-dilution Online Haemodiafiltration) was a multicenter, prospective, randomized, crossover study (NCT03611218) conducted at 6 German study sites between August and December 2018. Adult patients with chronic kidney failure and a minimum of 3 months on online HDF, fistula or graft as vascular access were randomized to polysulfone-based **FX CorAL 600** (Fresenius Medical Care), the polyarylethersulfone-based Polyflux 170H (Baxter), and the cellulose triacetate-based SureFlux 17UX (Nipro) each for 1 week.

Performance was assessed by removal rate and clearance of β 2-microglobulin, urea, creatinine, phosphate, myoglobin, and α 1-microglobulin. Hemocompatibility was assessed via markers of complement activation (C3a, C5a, sC5b-9), cell activation (leukocytes, polymorphonuclear elastase), contact activation (kallikrein), and coagulation (platelets, thrombin-antithrombin).

Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Results

Out of 70 recruited patients
(safety population), **58 patients**
(72% male, mean \pm SD age 68 ± 13 years)
were included in the efficacy analysis.



Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Performance

Highest least squares mean of β 2-microglobulin removal rate was shown for **FX CorAL 600 (70%)** and was superior to the SureFlux 17UX dialyzer (51%) and to Polyflux 17OH (68%). Clearance of β 2-microglobulin with **FX CorAL 600** was significantly higher than with SureFlux 17UX ($p < 0.001$). All three dialyzers performed similarly in terms of small molecule clearance of phosphate, urea and creatinine.



Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Hemocompatibility

FX CorAL 600 showed significantly lower peak levels of the complement factor sC5b-9 at 60 min compared to SureFlux 17UX ($p < 0.001$) and Polyflux 170H ($p = 0.02$). The differences persisted until end of treatment (Figure 1).

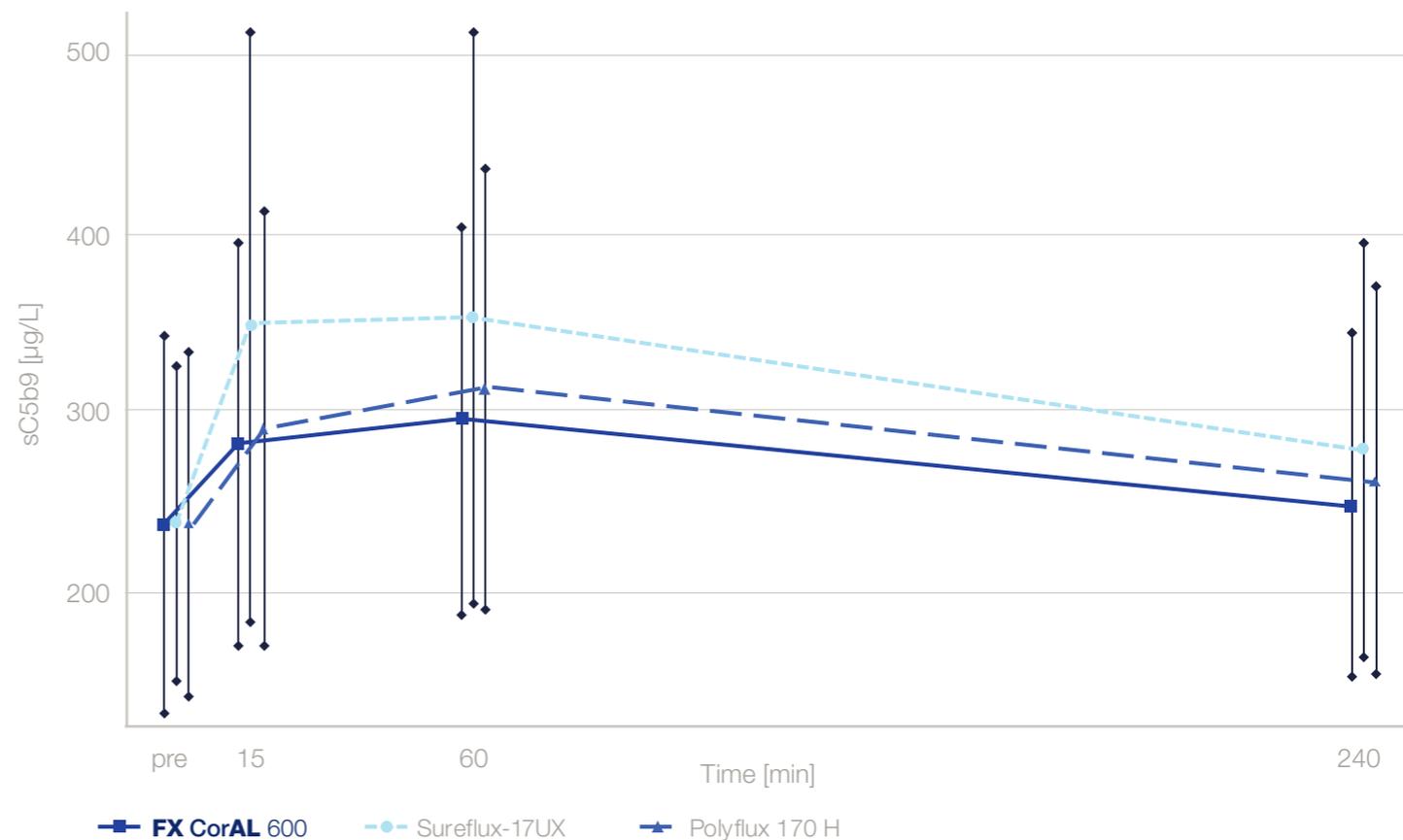


Figure 1: Course of plasma levels of complement factor sC5b-9 over the treatment period by investigated dialyzer (means \pm SD)

Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Hemocompatibility

With **FX CorAL 600**, peak levels of C3a and C5a at 15 min were significantly lower compared to SureFlux 17UX ($p < 0.001$ for C3a; $p = 0.02$ for C5a) and comparable to Polyflux 170H. Platelet count and thrombin-antithrombin concentrations implied no activation of coagulation and kallikrein levels showed no evidence of clinically relevant acute contact activation for any of the dialyzers.

FX CorAL 600 showed a less pronounced transient decrease in leukocyte levels (both $p < 0.001$) and a less pronounced increase in polymorphonuclear elastase than both comparators ($p = 0.002$ vs. Sureflux, $p < 0.001$ vs. Polyflux, Table 1).

Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Parameter	LSMean			P Value			
	FX CorAL 600	SureFlux 17UX	Polyflux 170H	Overall	A versus B	A versus C	B versus C
Change after 15 min							
Leukocytes (10 ⁹ /L)	-0.38	-0.87	-0.78	<0.001	<0.001	<0.001	0.40
Change after 240 min							
PMN elastase (ug/L)	16.33	19.34	25.83	0.002	0.26	<0.001	0.02
Platelets (10 ⁹ /L)	-15.3	-10.5	-23	<0.001	0.05	0.002	<0.001
TAT (ug/L)	6.90	5.06	4.02	0.81	0.68	0.52	0.82
Kallikrein (U/L)	5.13	11.09	10.85	0.16	0.09	0.11	0.95

LSMean, least squares mean; A, **FX CorAL 600**; B, SureFlux 17UX; C, Polyflux 170H; PMN, polymorphonuclear; TAT, thrombin-antithrombin III.

Table 1: Changes from baseline to 15 minutes (leukocytes) and 240 minutes for other markers of cell and coagulation activation, and contact activation

Performance and hemocompatibility of a novel polysulfone dialyzer: A randomized controlled trial

Ehlerding et al. *Kidney360*. 2021;2(6):937-947

Safety

The frequency of adverse events was low and comparable between all three dialyzers.

Conclusion

FX CorAL 600 efficiently removed small- and medium-sized molecules and showed a favorable hemocompatibility profile. The treatments with **FX CorAL 600** were well tolerated. The study was designed to analyze possible acute effects of the membrane material during dialysis treatment and cannot provide conclusions on long-term effects on patient outcomes.



Randomized comparison of three high-flux dialyzers during high-volume online hemodiafiltration-the comPERFORM study

Ehlerding et al. Clin Kidney J. 2022 Oct 5;15(4):672-680

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Randomized comparison of three high-flux dialyzers during high-volume online hemodiafiltration-the comPERFORM study

Ehlerding et al. Clin Kidney J. 2022 Oct 5;15(4):672-680

Background

The accumulation of small and middle molecular weight uremic solutes is associated with increased mortality risk of patients with end-stage renal disease. Therefore, hemodialyzers are designed to efficiently eliminate uremic toxins during dialysis treatment. The dialyzer's membrane is mainly responsible for the selective sieving of molecules. While clearance of large amounts of uremic toxins of medium molecular size, such as β 2-microglobulin (11.8 kDa) is desired, a permeability cut-off should be maintained to prevent the loss of essential proteins such as albumin (66 kDa) during hemodialysis or hemodiafiltration (HDF). **FX CorAL** is a novel dialyzer with increased polyvinylpyrrolidone (PVP) content on its blood-side surface. To prevent PVP oxidation and elution, it is stabilized with a small amount of α -tocopherol.

Objective

To investigate efficacy (clearances and removal rates of β 2-microglobulin and other uremic toxins) and safety (adverse events) of **FX CorAL** compared with two comparators and to characterize the dialyzers' albumin sieving properties.

Randomized comparison of three high-flux dialyzers during high-volume online hemodiafiltration-the comPERFORM study

Ehlerding et al. Clin Kidney J. 2022 Oct 5;15(4):672-680

Methodology

comPERFORM (Comparative Clinical Performance of Dialyzers Applied During High Volume Online Haemodiafiltration) was a prospective, open, controlled, multicentric, interventional, crossover study with randomized treatment sequences (NCT04102280). Between October 2019 and November 2020, stable patients receiving regular post-dilution online HDF were randomized to **FX CorAL 600** (Fresenius Medical Care Deutschland), xevo Hi 15 (B. Braun) and ELISIO 150H (Nipro) each for 1 week. The primary outcome was the β 2-microglobulin removal rate

during 4-hour sessions of online HDF. β 2-microglobulin was determined at the mid-week dialysis session of each trial period pre-HDF and 60 min and 240 min after its start. Secondary endpoints were removal rate and clearance of β 2-microglobulin, myoglobin, phosphate, creatinine, phosphate and urea. Albumin removal over time was an exploratory endpoint, calculated from albumin concentrations determined pre-HDF and 15, 30, 60, and 240 min during HDF. Non-inferiority and superiority of **FX CorAL 600** versus comparators were tested.

Randomized comparison of three high-flux dialyzers during high-volume online hemodiafiltration-the comPERFORM study

Ehlerding et al. Clin Kidney J. 2022 Oct 5;15(4):672-680

Results

In total, 52 patients (85% male, mean \pm SD age 64.8 \pm 14.5 years) were included in the study. In terms of β 2-microglobulin removal rate, **FX CorAL 600** (75.47%) was significantly superior to both xevonta Hi 15 (74.01%, $p=0.0216$) and ELISIO 150H (72.70%, $p<0.0001$) (Figure 1). Similarly, **FX CorAL 600** was significantly superior to both comparators ($p=0.0010$ and $p=0.0019$, respectively) in β 2-microglobulin clearance at 60 min after the start of HDF. Regarding myoglobin removal rate, **FX CorAL 600** performance was superior to both comparators ($p<0.0001$ and $p=0.0015$) (Figure 1); in terms of myoglobin clearance, **FX CorAL 600** was superior to xevonta Hi 15 ($p=0.0004$) and comparable to ELISIO 150H. Removal rates and clearances of the small molecules creatinine, phosphate

and urea were similar between dialyzers. **FX CorAL 600** demonstrated the lowest amount of albumin removal up to 60 min ($p<0.03$ at 15, 30 and 60 min versus both comparators) and its sieving properties changed less over time than those of the comparators), indicating a stable performance profile throughout therapy. The safety profile of all three dialyzers was comparable and within the known scope.

Randomized comparison of three high-flux dialyzers during high-volume online hemodiafiltration-the comPERFORM study

Ehlerding et al. Clin Kidney J. 2022 Oct 5;15(4):672-680

Conclusion

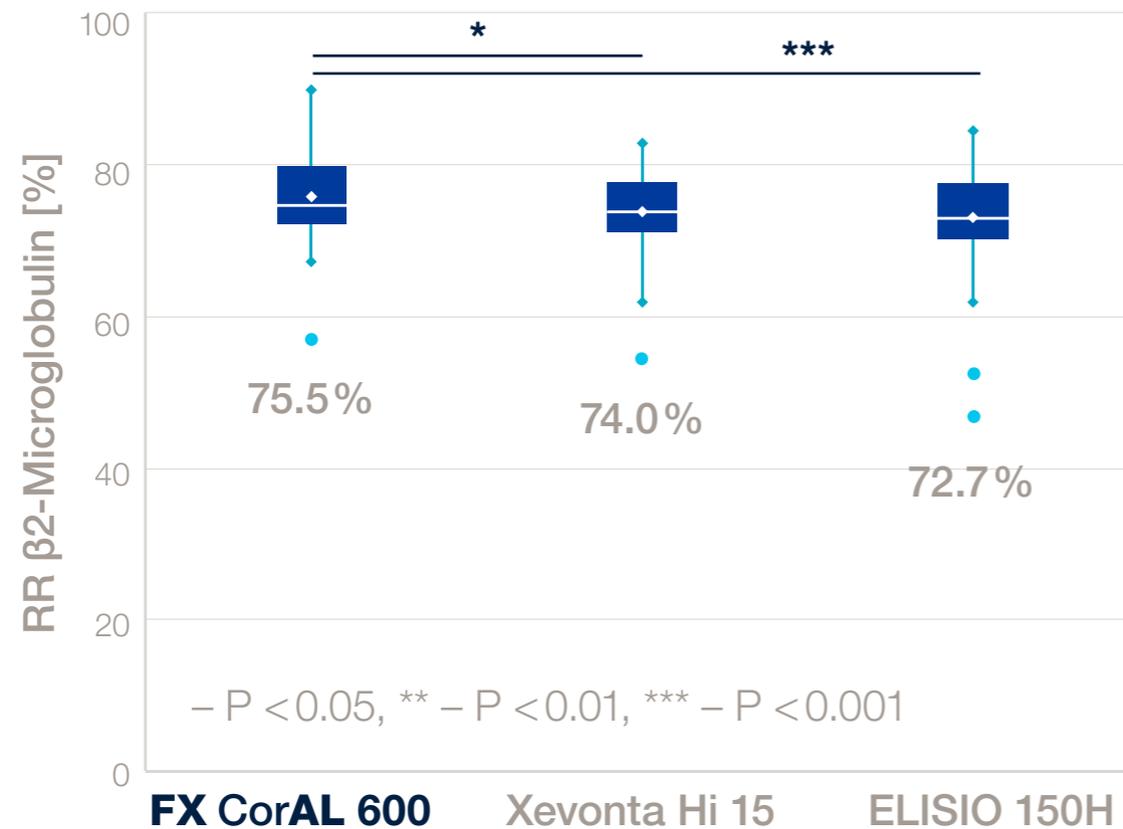
FX CorAL 600 was superior to the two comparator dialyzers in removing β_2 -microglobulin and myoglobin over 4-hour online HDF sessions and in β_2 -microglobulin clearance, measured 60 min after the start of HDF. It efficiently removed and cleared the small molecules creatinine, phosphate and urea as well. HDF sessions with **FX CorAL 600** were well tolerated. The reduced albumin adsorption seen over the first hour with **FX CorAL 600** is thought to originate from the dialyzer membrane's almost neutral surface charge and its higher PVP concentration on the inner surface, which stabilizes a membrane-protective hydrolayer, thus leading to reduced formation of a secondary membrane.



Randomized comparison of three high-flux dialyzers during high-volume online hemodiafiltration-the comPERFORM study

Ehlerding et al. Clin Kidney J. 2022 Oct 5;15(4):672-680

β 2-microglobulin



Myoglobin

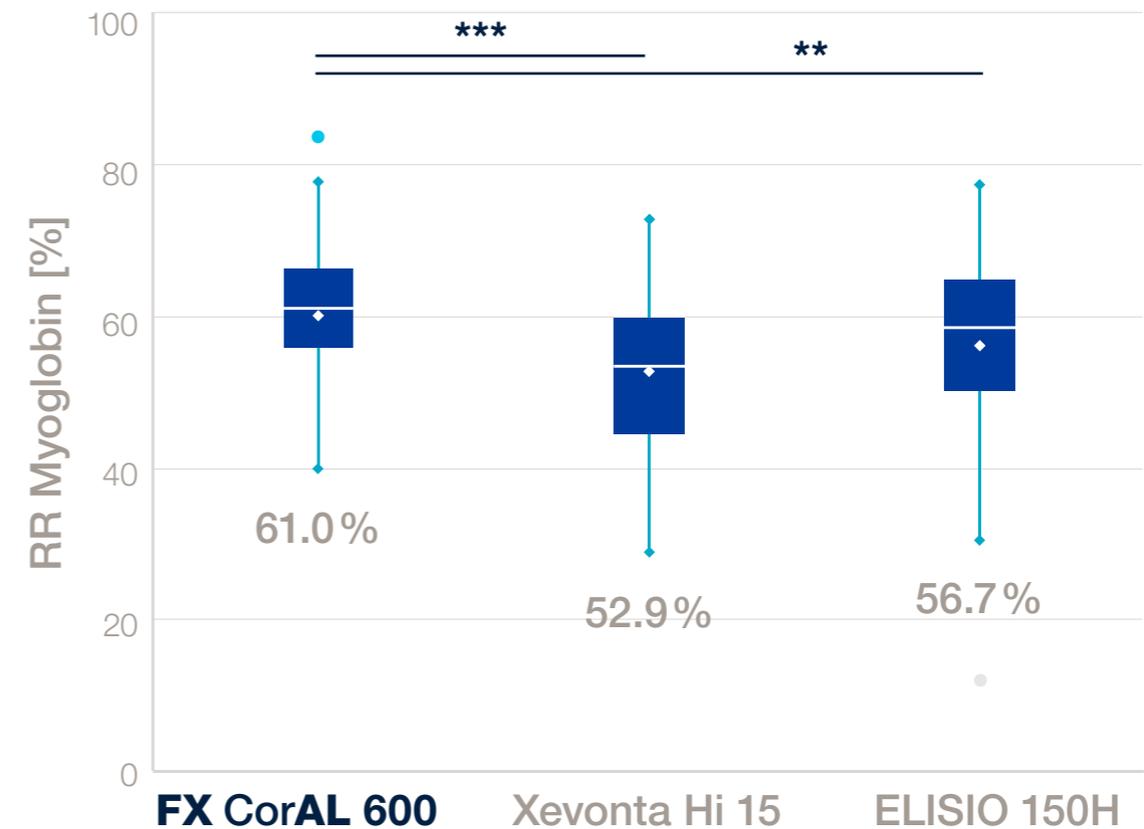


Figure 1: Removal rate of β 2-microglobulin and myoglobin over time by dialyzer (ITT population; LS mean \pm standard error).

Real-World Clinical Performance Evaluation of the FX CorAL dialyzer: A retrospective cohort study

Background

Objective

Methodology

Results

Conclusion

Wolf et al. Virtual poster presentation at Kidney Week, Nov 4, 2021

Real-World Clinical Performance Evaluation of the FX CorAL dialyzer: A retrospective cohort study

Wolf et al. Virtual poster presentation at Kidney Week, Nov 4, 2021 / PO0793

Background

The function of a dialyzer depends on the clearance described in the Instructions for Use by the manufacturers. However, these clearance values are measured in an aqueous solution that does not contain any plasma proteins. Thus, the in-vitro clearances of a dialyzer may not necessarily reflect clinical practice, and the in-vivo dialyzer performance is more relevant in clinical reality. The performance profile of a dialyzer has a huge impact on the long-term treatment of patients with end-stage renal disease (ESRD), as it affects the risk of cardiovascular and inflammatory complications.

Treatment characteristics, such as treatment duration, blood and dialysate flow rates, have a direct impact on the hemodynamics of the patients by influencing their blood pressure and leading to potential reactions of endothelial tissue in addition to the immunomodulatory reactions related to the dialyzer membrane properties. Together with urea reduction ratio and dialysis adequacy (Kt/V), which reflect the uremic toxin removal performance of the dialyzer membrane, these clinical performance parameters provide real-world data on the quality of the investigated dialyzers.

Real-World Clinical Performance Evaluation of the FX CorAL dialyzer: A retrospective cohort study

Wolf et al. Virtual poster presentation at Kidney Week, Nov 4, 2021

Objective

To evaluate differences in the clinical therapy performance parameters of therapy sessions with two dialyzers with different clearances in a real-world setting.

Methodology

A total of 51 NephroCare dialysis centers (33 in Portugal and 18 in Hungary) were randomly allocated to a temporal sequence of dialyzer switches from FX CorDiax to **FX CorAL**. The clinics used predominantly the FX CorDiax dialyzer prior to switching to **FX CorAL**. The European Clinical Database (EuCliD[®]) data of 1924 adult patients, who were switched from FX CorDiax to **FX CorAL** between July 2020 and January 2021, were analyzed. To evaluate the clinical performance, intra-individual changes of various parameters between three months before and three months after the dialyzer switch were compared using paired t-test or Wilcoxon signed-rank test.

Real-World Clinical Performance Evaluation of the FX CorAL dialyzer: A retrospective cohort study

Wolf et al. Virtual poster presentation at Kidney Week, Nov 4, 2021

Results

The patients had a median age of 70 years, were predominantly male (64.2%), 38.4% of them suffered from diabetes and 63.3% were hypertensive. The median dialysis vintage was 55.1 months. The majority of patients were treated with online hemodiafiltration (88.6%) and 75.3% had an arterio-venous fistula as vascular access for the treatment. After switching to the **FX CorAL** dialyzer, the mean dialysate flow was slightly reduced (0.57%) and an increase in the effective

treatment time of 4.2 min (1.8%) as well as an increase in the online clearance parameter Kt/V of 0.05 (2.7%) was observed. Among patients treated with hemodiafiltration, the effective infusion and convective volume increased by approximately 0.5 L (2.1%). The urea reduction ratio increased by 1.29 (1.6%) indicating slightly improved performance of the **FX CorAL** compared to FX CorDiax. All changes were statistically significant (Table 1).

Real-World Clinical Performance Evaluation of the FX CorAL dialyzer: A retrospective cohort study

Wolf et al. Virtual poster presentation at Kidney Week, Nov 4, 2021

Conclusion

After the switch, slight, but statistically significant changes in performance parameters in favor of the **FX CorAL** dialyzer

were observed. More analyzes will be needed to conclude robust clinical benefits from switching to **FX CorAL**.

	FX CorDiox	Change using FX CorAL	Paired-test / Wilcoxon
Mean blood flow [ml/min]	399.43 (48.49)	-0.58 [-1.45; 0.30]	<.0001
Dialysate flow [ml/min]	420.33 (56.18)	-2.41 [-3.37; -1.45]	<.0001
Effective treatment time [min]	235.06 (18.73)	4.21 [3.80; 4.63]	<.0001
Effective infusion (HDF) [l]	23.18 (4.56)	0.48 [0.37; 0.59]	<.0001
Convective volume (HDF) [l]	25.33 (4.53)	0.54 [0.44; 0.65]	<.0001
Single-Pool Variable-Volume Kt/V	1.94 (0.33)	0.09 [0.07; 0.11]	<.0001
Urea reduction ratio [%]	79.93 (5.24)	1.29 [0.96; 1.63]	<.0001
Equilibrated Kt/V	1.66 (0.29)	0.09 [0.07; 0.11]	<.0001
Online Clearance Monitoring Kt/V	1.80 (0.39)	0.05 [0.04; 0.06]	<.0001

Table 1: Treatment characteristics before and after the change from FX CorDiox to **FX CorAL** dialyzer.

Data are shown as mean (SD) using FX CorDiox and their change [95% confidence interval] after the switch to **FX CorAL**.

Hemodiafiltration: Technical and Medical Insights

Lang et al. Bioengineering (Basel). 2023 Jan 21;10(2):145

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Hemodiafiltration: Technical and Medical Insights

Lang et al. Bioengineering (Basel). 2023 Jan 21;10(2):145

Background

Patients with end-stage kidney disease (ESKD) suffer from high mortality and numerous comorbidities, with most relying on hemodialysis (HD) or hemodiafiltration (HDF) for renal replacement therapy. **HDF**, which combines diffusion and convection to remove a broader range of uremic toxins, has demonstrated **superior toxin clearance compared to HD**.

This review article discusses the **technical aspects of HDF**, including dialyzer and machine considerations, as well as the **clinical evidence supporting its efficacy**. It also highlights **ongoing clinical trials** focused on **improving patient outcomes and quality of life**.



Hemodiafiltration: Technical and Medical Insights

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Technical Insights

HDF, which combines the principles of hemodialysis (HD) and hemofiltration (HF), enhances solute removal by utilizing both diffusive and convective mechanisms, **requiring** a **substitution fluid**, **hemodiafilter**, and **HDF machine** to optimize treatment performance.

1. Substitution fluid

HDF uses ultrafiltration to remove plasma water, which is then replaced with a sterile substitution fluid, with **modes** such as **post-dilution**, **pre-dilution**, **mixed-dilution**, and **mid-dilution**.

In **post-dilution HDF**, the **fluid is infused downstream**, offering **high convective clearance** but increasing the **risk of membrane fouling** and **blood viscosity**.

Pre-dilution HDF infuses the **fluid upstream** to reduce the risk of clotting and membrane fouling but **requires larger substitution volumes for equivalent clearance**.

Mixed-dilution and **mid-dilution** combine both techniques to optimize solute removal depending on patient needs.

Sterilization of the **substitution fluid** is achieved during treatment by a **two-stage ultrafiltration process**, ensuring the fluid remains **safe** and **contaminant-free**.

Hemodiafiltration: Technical and Medical Insights

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Technical Insights

2. Hemodiafilter

Hemodiafilters used in **HDF** differ from standard HD dialyzers by **requiring a sharp sieving coefficient curve, high permeability, and optimized fiber geometry** to enhance performance.

- A **steep sieving coefficient** curve ensures **effective removal of middle-sized molecules**, like β 2-microglobulin, while **minimizing albumin loss** to prevent malnutrition, as seen in the example of **FX CorAL** (Figure 1). Its steeper slope and earlier molecular weight cut-off allow effective middle molecule removal while minimizing albumin loss, making it the optimal choice for HDF compared to membranes 2 and 3.

- **High permeability** is essential for **achieving the large ultrafiltration volumes** needed in high-volume (HV) HDF, making high-flux dialyzers necessary.
- **Fiber geometry** with **larger inner diameters (>200 μ m)** helps **address increased blood viscosity during HDF** by reducing flow resistance, preventing clogging, and enabling higher convective volumes.

Membrane materials range from synthetic polymers like polysulfone to cellulose triacetate, offering **diverse options for optimizing HDF** treatments. This careful balance of design features ensures maximum toxin removal while preserving essential proteins and maintaining efficient flow dynamics.

Hemodiafiltration: Technical and Medical Insights

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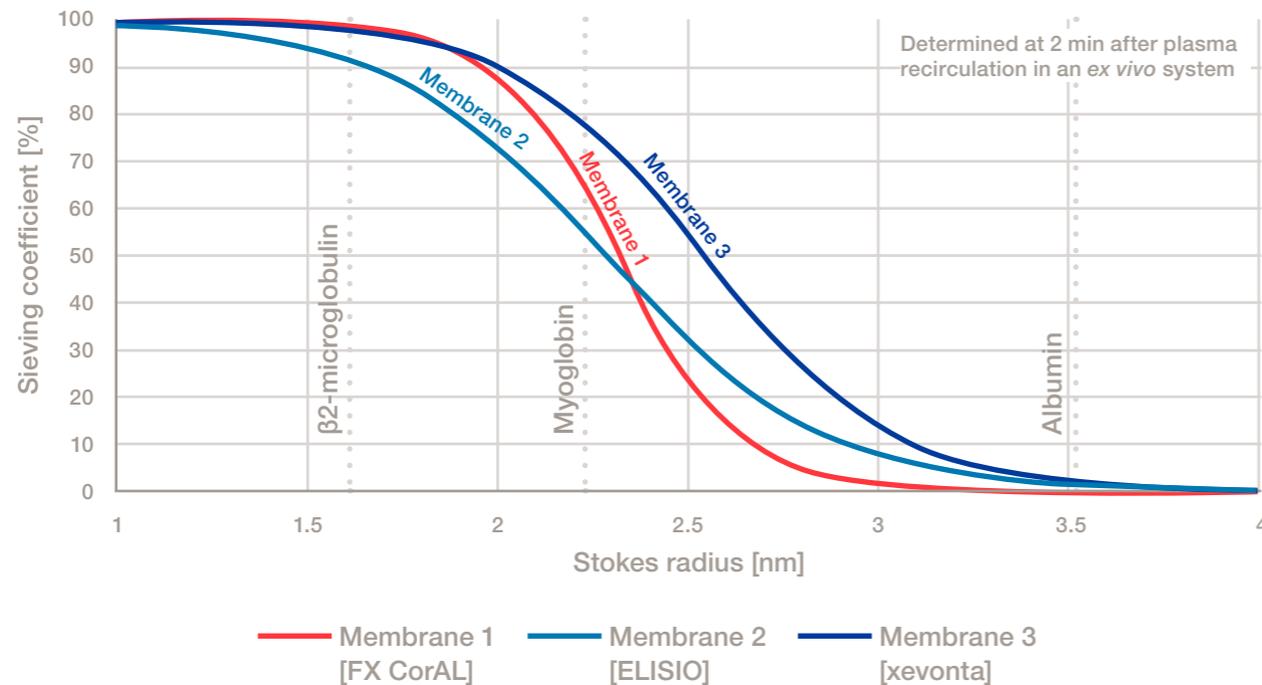


Figure 1. Schematic illustration of sieving coefficients as a function of Stokes radius for three different dialysis membranes. The sieving profiles were determined 2 min after plasma recirculation in an ex vivo system and differ in terms of retention properties across the range of solutes up to the size of albumin. Data were reanalyzed from recently published data [24] (n = 3 for each membrane; membrane 1: FX CorAL [Fresenius Medical Care]; membrane 2: ELISIO [Nipro]; membrane 3: xevonta [B. Braun]).

Hemodiafiltration: Technical and Medical Insights

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Technical Insights

3. HDF Machine

HDF treatments rely on advanced dialysis **machines** to ensure **high substitution fluid volumes** while maintaining treatment stability. **High transmembrane pressures** from large infusion volumes can cause instability, interruptions, and protein losses, necessitating innovations in infusion rate control. Early HDF relied on prefilled substitution fluid bags, limiting infusion volumes, but online preparation of sterile, pyrogen-free fluids allowed for larger volumes.

Systems like **UltraControl™** and **AutoSub plus™** use **pressure-based biofeedback** to **optimize infusion rates** by continuously monitoring transmembrane pressure (TMP) and membrane stress. These systems **simplify HDF**, **maximize substitution rates**, and **reduce albumin loss**, especially in the early treatment phase, when most albumin loss typically occurs.

Additional feedback systems, such as **Max Sub™** and **KUF Max™**, **individualize filtration rates** to improve safety and efficiency, addressing challenges like hemoconcentration and clotting through continuous monitoring and automated adjustments.

Hemodiafiltration: Technical and Medical Insights

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Technical Insights

Impact of Protein Fouling of the Membrane on Substitution Volume

During HDF treatments, **protein adsorption** on the dialysis membrane forms a **secondary barrier** that reduces membrane permeability and **requires higher transmembrane pressure** (TMP) to maintain filtration. This **effect is more pronounced in HDF** than HD due to the higher transport rate of plasma proteins, leading to reduced solute removal and substitution volumes.

Hydrophilic modifications to synthetic membranes, such as blending with polyvinylpyrrolidone (PVP), **minimize protein fouling** and improve performance stability by **reducing TMP increases**. **Dialyzers** with **higher PVP** content show **better removal** efficiency for **middle molecules** like β 2-microglobulin and maintain **consistent filtration** over time.

To **optimize substitution volumes**, factors like **blood flow**, **anticoagulation**, **TMP management**, and **patient-specific characteristics** must also be **considered**.

Hemodiafiltration: Technical and Medical Insights

Lang et al. Bioengineering (Basel). 2023 Jan 21;10(2):145

Medical Insights

Necessity of Advanced Treatment Options for ESKD Patients to Improve Outcomes

Patients with **ESKD** face **high morbidity and mortality rates**, with common comorbidities including metabolism and nutrition disorders, diabetes mellitus, hypertension, and cardiovascular complications.

Cardiovascular disease is the leading cause of death, with male dialysis patients experiencing significantly higher myocardial infarction and mortality rates compared to the general population.

Protein-energy wasting (PEW), driven by anorexia, under-dialysis, and protein loss, is a **major predictor of poor outcomes**. Achieving **recommended dialysis target doses** and **utilizing efficient modalities** can **reduce PEW** by improving protein uptake and minimizing albumin loss.

Effective dialysis should focus on **removing uremic toxins** while **preserving essential proteins** to improve clinical outcomes.

Hemodiafiltration: Technical and Medical Insights

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Medical Insights

HDF vs. Other Modalities: Impact on Performances as Short-Term Surrogate Marker of Efficiency

HDF is preferred in Europe and Asia due to its superior performance compared to HD, including better uremic toxin removal, improved hemodynamic stability, and reduced inflammation.

Post-dilution HDF achieves the highest clearance rates for middle molecular weight toxins, outperforming HDx and other modalities, though HDx with MCO membranes offers an alternative with nominally similar clearance and lower albumin loss.

HDF also shows benefits in reducing insulin resistance and inflammation due to its enhanced elimination of inflammatory compounds.

Efficient HDF requires high-quality, high-flux dialyzers with synthetic hydrophilic membranes for optimal performance and minimal protein fouling. Studies highlight the variability in dialyzer performance, with polysulfone membranes generally achieving higher β 2-microglobulin reduction rates compared to cellulose-based membranes.

Hemodiafiltration: Technical and Medical Insights

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Medical Insights

Impact on Morbidity and Mortality as Hard Clinical Endpoint to Support Larger Use of HDF

High-volume HDF has been associated with **improved clinical outcomes**, including **lower all-cause** and **cardio-vascular mortality** rates, compared to standard HD.

Meta-analyses of RCTs, such as the European pooling project, demonstrated a **dose-response relationship**, with a **convection volume >23 L per session leading to significant reductions in mortality**.

Observational studies in Europe and Japan **further supported the superiority of high-volume HDF**, with rapid and sustained survival benefits noted, particularly for cardiac-related deaths.

However, some **studies**, including those focusing on **elderly patients**, found **no significant differences**, highlighting the **potential influence of patient-specific factors and clinical practices**.

Overall, high-volume HDF is recommended for its **survival benefits**, especially in reducing cardiac mortality.

Hemodiafiltration: Technical and Medical Insights

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Medical Insights

Mechanisms for Beneficial Effects of HDF

The **survival benefits** of HDF are likely due to a combination of **direct and indirect effects** on **cardiovascular function and structure**.

Direct effects include:

- Improved hemodynamic stability
- Reduced intradialytic hypotension
- Decreased inflammation, oxidative stress, and progression of atherosclerosis
- Better endothelial function
- Reduced arrhythmogenicity



Hemodiafiltration: Technical and Medical Insights

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Medical Insights

Mechanisms for Beneficial Effects of HDF

Indirect effects involve improved:

- Anemia correction
- Nutritional status
- Physical activity
- Quality of life
- Preservation of residual kidney function

These mechanisms collectively improve outcomes, though individual contributions are hard to isolate.

Low serum albumin, diabetes, and high comorbidity may hinder achieving high convective volumes linked to better survival

Hemodiafiltration: Technical and Medical Insights

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Conclusions

- In summary, **both technical and clinical factors are crucial for treating ESKD patients** with **HDF**, with membrane characteristics and machine settings playing a role in achieving optimal convection volumes.
- **Lower protein adsorption** to membranes may enhance filtration and **improve treatment outcomes**, particularly for high-volume HDF, which is associated with better mortality and cardiovascular disease outcomes. However, variations in clinical practices also impact results.
- Future studies, including ongoing trials like CONVINCe and H4RT, will explore patient-reported outcomes and economic aspects, aiming to solidify the benefits of high-dose HDF and optimize renal replacement therapy for ESKD patients.

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

Background

Objective

Methodology

Results

Conclusions

Maduell F, et al. Membranes (Basel). 2025 Jan 14;15(1):30

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

Maduell F, et al. Membranes (Basel). 2025 Jan 14;15(1):30

Background

Synthetic high-flux dialyzers, primarily composed of poly-sulfone and polyethersulfone, are widely used in hemodialysis (HD) and online hemodiafiltration (HDF) due to their effective solute removal and biocompatibility.

To enhance hemocompatibility and reduce adverse reactions, newer hydrophilic membrane technologies – such as Hydrolink® NV and **FX CorAL**® – have been developed, offering improved antithrombotic properties and reduced protein fouling.

Objective

This study compared prospectively both hydrophilic membranes by assessing the performance and albumin loss of the Hydrolink NV dialyzer in HD and post-dilution HDF at different infusion flows (Q_{is}), and the **FX CorAL** dialyzer in post-dilution HDF.

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

Maduell F, et al. Membranes (Basel). 2025 Jan 14;15(1):30

Methodology

This prospective, single-center study of 20 patients, included five dialysis sessions with **FX CorAL** 800 and Toraylight NV 2.1, under the following conditions:

1. Toraylight NV 2.1 in HD
2. Toraylight NV 2.1 in post-dilution HDF with infusion flow (Qi) 50 mL/min
3. Toraylight NV 2.1 in post-dilution HDF with Qi 75 mL/min
4. Toraylight NV 2.1 in post-dilution HDF with Qi in auto-substitution
5. FX CorAL 800 in post-dilution HDF with Qi in auto-substitution

It investigated the difference between **FX CorAL** 800 and Toraylight NV 2.1 in regard to:

- **Performance** (GRS and RR of Urea, Creatinine, β 2M, Myoglobin, κ -FLC, λ -FLC, Prolactin, α 1M, α 1GP, IS, pCS)
- **Albumin** (RR and Loss)

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

Maduell F, et al. Membranes (Basel). 2025 Jan 14;15(1):30

Results

- **Small-sized molecules:**
Slightly lower urea and creatinine removal rates in HD vs. all HDF modalities.
- **Medium-sized molecules:**
Removal of β 2-M, myoglobin, Λ -FLC, prolactin, α 1-M, and α 1-GP increased with higher Q_i , with Toraylight NV generally outperforming **FX CorAL** in auto-substitution HDF.
- **PBUT:**
IP and p-CS removal ranged from 40–60%, increased with higher Q_i , and showed no differences between dialyzers in auto-substitution, with minimal contribution from albumin-bound fractions.

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

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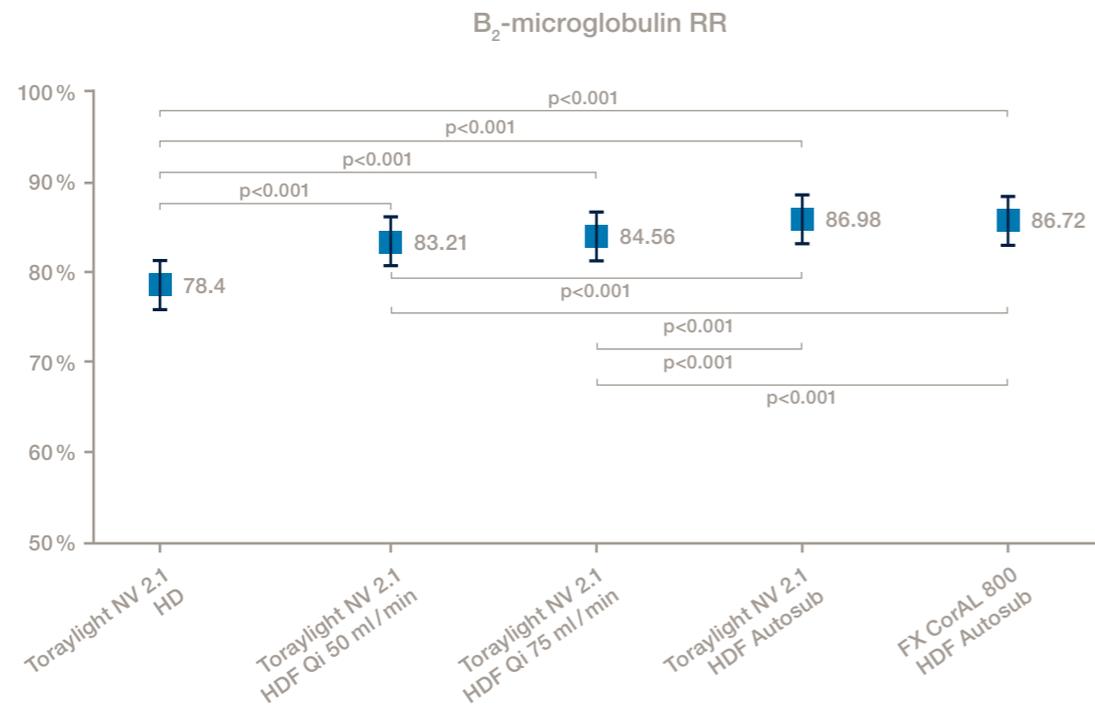


Figure 1. Comparison of the β 2-microglobulin RRs in all study situations.

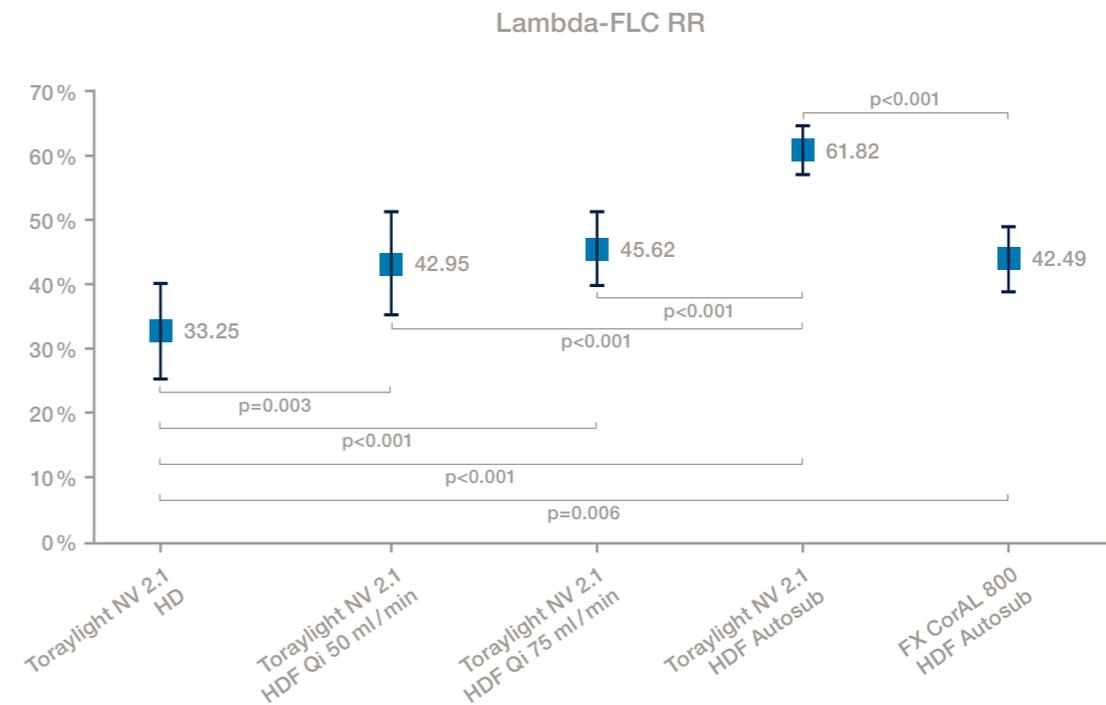


Figure 2. Comparison of the lambda free immunoglobulin light chains RRs in all study situations.

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

Maduell F, et al. Membranes (Basel). 2025 Jan 14;15(1):30

Results

- **Albumin loss:**
Albumin retention similar across treatments, however highest loss was with Toraylight NV in auto-substitution HDF (>5 g in >50% of patients), and strongly correlated with Qi and convective volume.
- **GRS:**
Highest GRS with Toraylight NV in auto-substitution HDF, followed by **FX CorAL** in auto-substitution, with all HDF treatments outperforming HD.



A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

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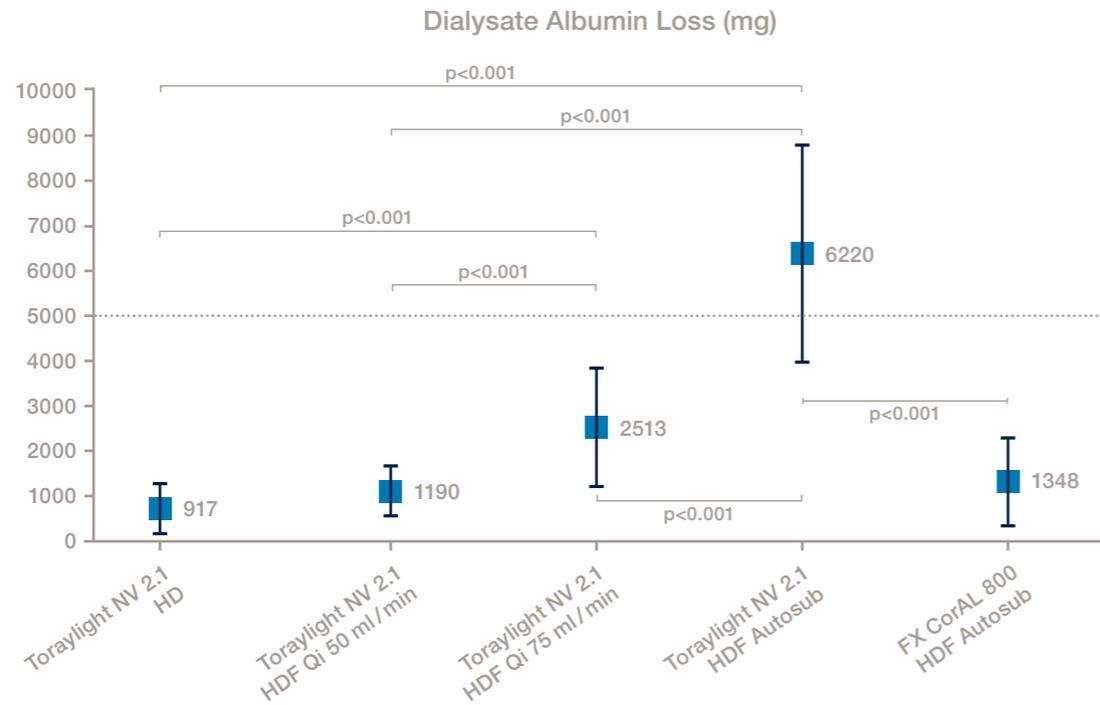


Figure 3. Comparison of dialysate albumin loss in all study situations.

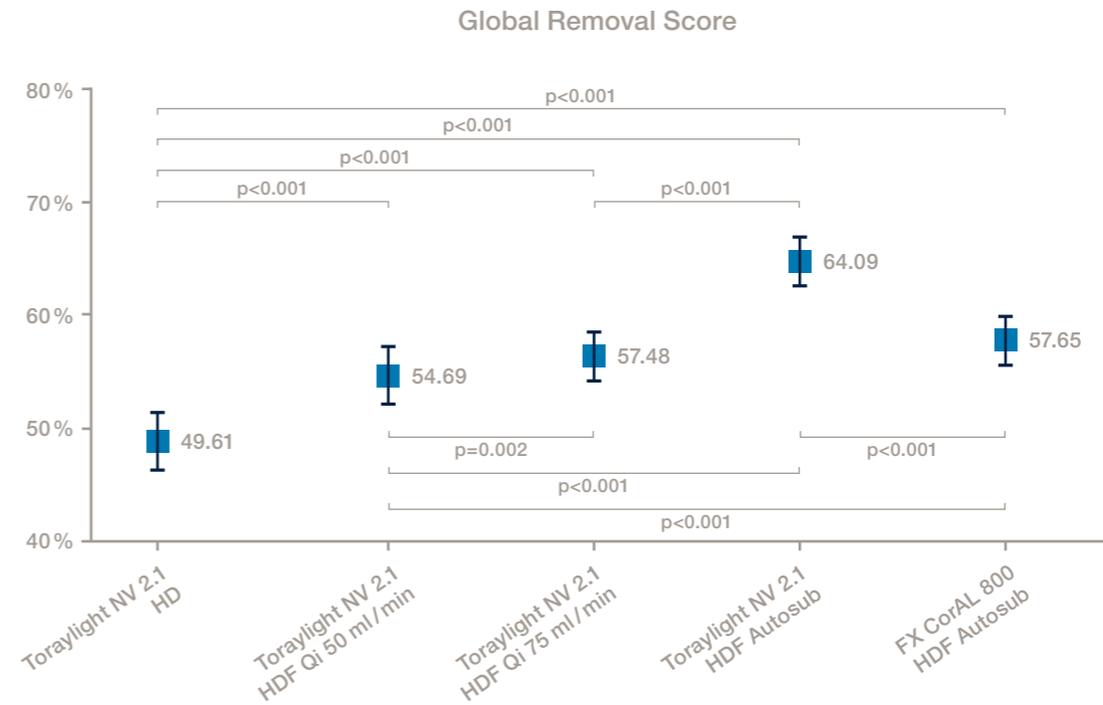


Figure 4. Comparison of the global removing score in all study situations.

A Study on the Safety and Efficacy of an Innovative Hydrophilic Dialysis Membrane

Maduell F, et al. Membranes (Basel). 2025 Jan 14;15(1):30

Conclusions

- While effective, the Toraylight NV 2.1 dialyzer requires careful adjustment of convective parameters to ensure treatment safety.
- Current findings support limiting Qi and FF values when using an MCO membrane, but further studies are needed to strengthen these recommendations.



Polysulfone hemodia- filtration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

Background >

Objective and Methodology >

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Zhu L, et al. Mater Sci Eng C Mater Biol Appl. 2017 May 1;74:159-166

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

Zhu L, et al. Mater Sci Eng C Mater Biol Appl. 2017 May 1;74:159-166

Background

Polysulfone (PSf) membranes are valued for their strength, stability, and chemical resistance in biomedical applications. However, their hydrophobicity causes poor antifouling and hemocompatibility, leading to protein adsorption, platelet adhesion, and thrombus formation.

Thus, special hydrophilic modifications have been developed, particularly via polyvinylpyrrolidone (PVP) incorporation or in situ polymerization, that effectively enhance membrane antifouling, hemocompatibility, and long-term durability.

Objective and Methodology

This study aimed to enhance the antifouling and hemocompatibility of PSf membranes via in situ crosslinked polymerization of VP and vinyltriethoxysilane (VTEOS), followed by membrane fabrication using the NIPS technique.

The resulting membranes were characterized for morphology, surface chemistry, hydrophilicity, fouling resistance, protein adsorption, platelet interactions, and key hemocompatibility indicators such as APTT, PT, and fibrinogen conversion.

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

Zhu L, et al. Mater Sci Eng C Mater Biol Appl. 2017 May 1;74:159-166

Results

- **Membrane chemistry and morphology:**
SEM analysis showed that **copolymer addition enlarged finger-like pores, reduced skin layer thickness, and increased porosity**, significantly altering membrane morphology.
- **Membrane hydrophilicity:**
Water contact angle measurements revealed that the **modified membranes** exhibited much lower initial angles and faster decay, indicating **improved hydrophilicity**.
This **enhancement was mainly attributed to the introduction of PVP** chains and silanol groups from the copolymer.

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

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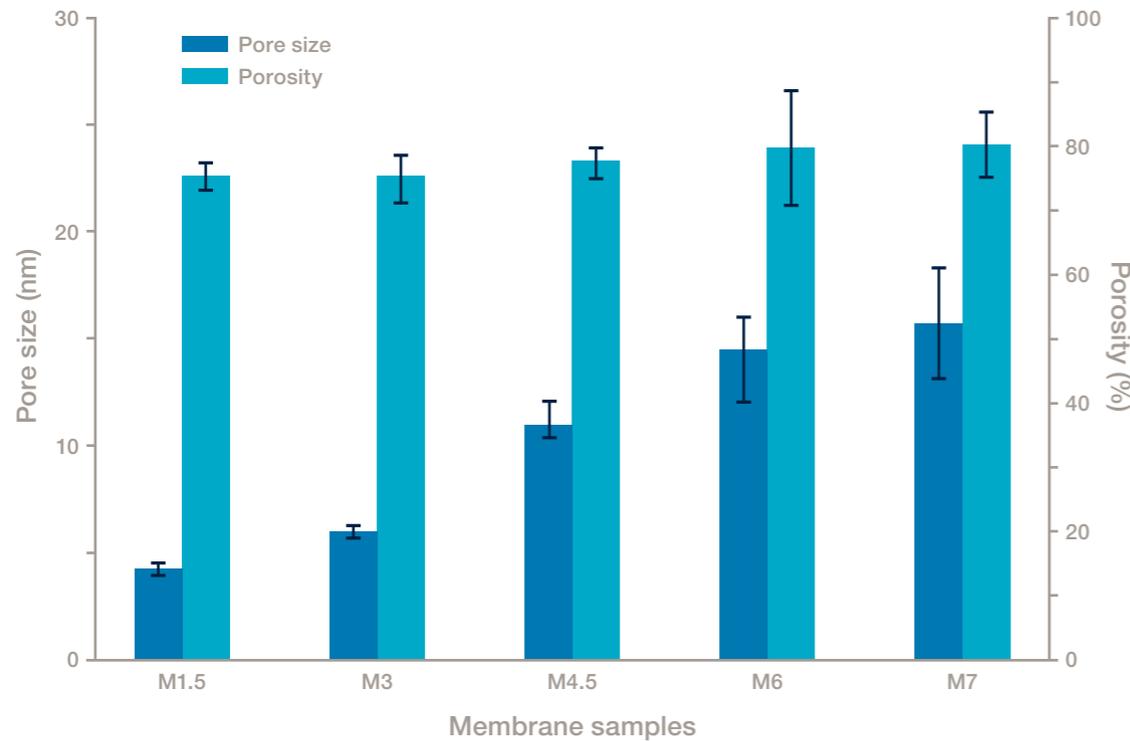


Figure 1. Pore size and porosity of the modified PSf membranes

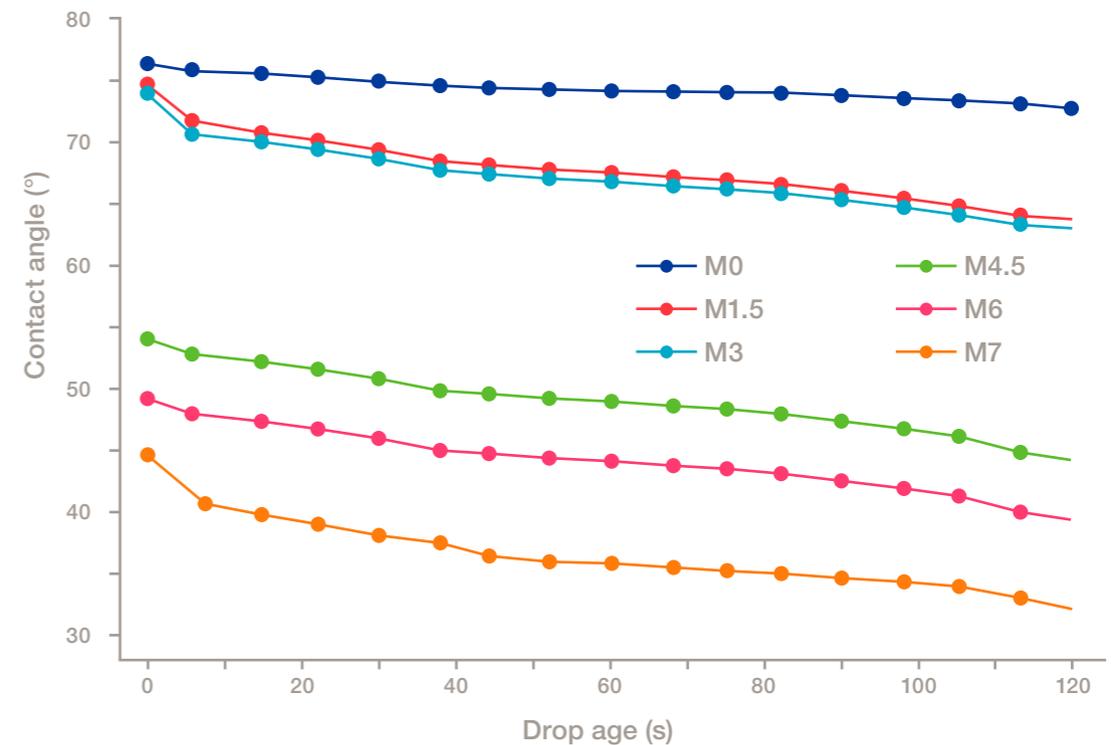


Figure 2. The typical curves of water contact angle decaying with drop age for the PSf membranes

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

Zhu L, et al. Mater Sci Eng C Mater Biol Appl. 2017 May 1;74:159-166

Results

- **Filtration and anti-fouling performances:**

Modified membranes demonstrated higher pure water flux, improved flux recovery ratios, and reduced protein adsorption compared to pristine PSf, indicating **enhanced antifouling ability**.

The **improvements were driven by increased pore size, better hydrophilicity, and electrostatic repulsion**, with M6 showing the best balance between permeability and selectivity.



Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

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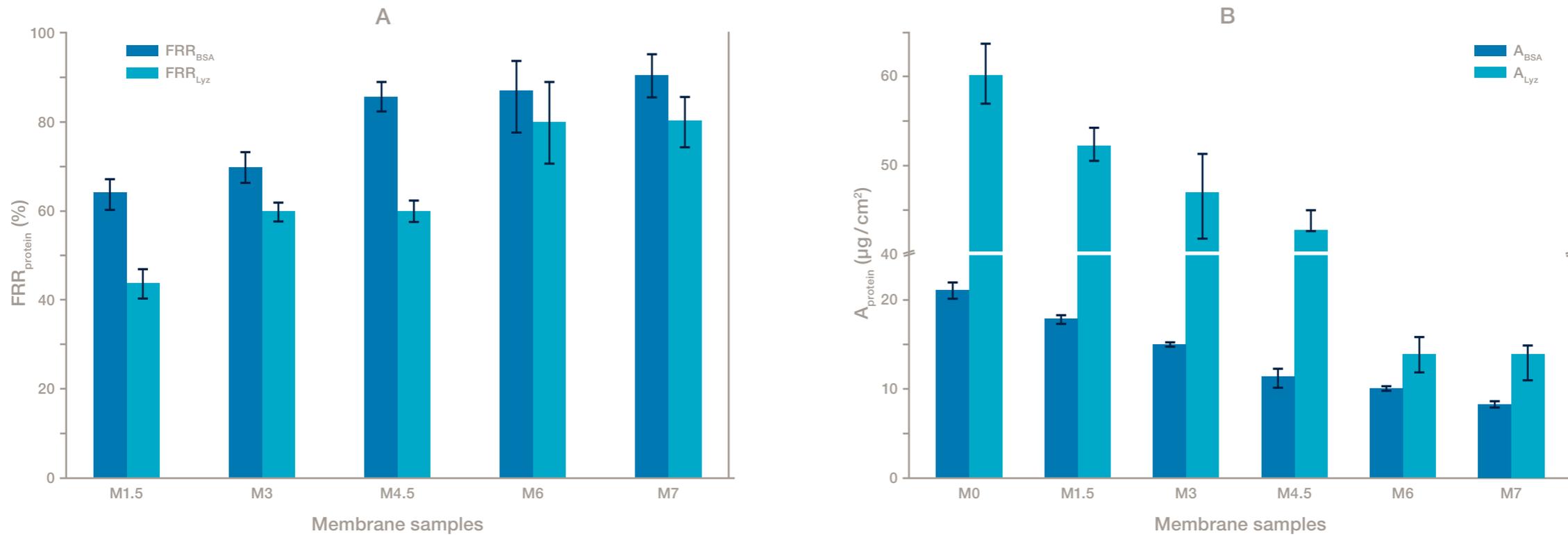


Figure 3. (A) Flux recovery ratio (FRR_{protein}) and (B) adsorbed protein (A_{protein}) of the PSf membranes.

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

Zhu L, et al. Mater Sci Eng C Mater Biol Appl. 2017 May 1;74:159-166

Results

- **Hemocompatibility:**

The modified membranes exhibited reduced platelet adhesion and activation, along with prolonged APTT and PT values and decreased fibrinogen conversion, **indicating improved blood compatibility.**

These **results were attributed to the hydrophilic surface preventing protein and platelet interactions with the membrane.**

- **Comparisons of different hemodiafiltration membranes:**

Compared with commercial HDF membranes, **M6 showed superior antifouling and hemocompatibility**, with lower BSA adsorption and prolonged coagulation times. Additionally, it effectively retained albumin while removing middle molecules, demonstrating strong potential for clinical application.

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

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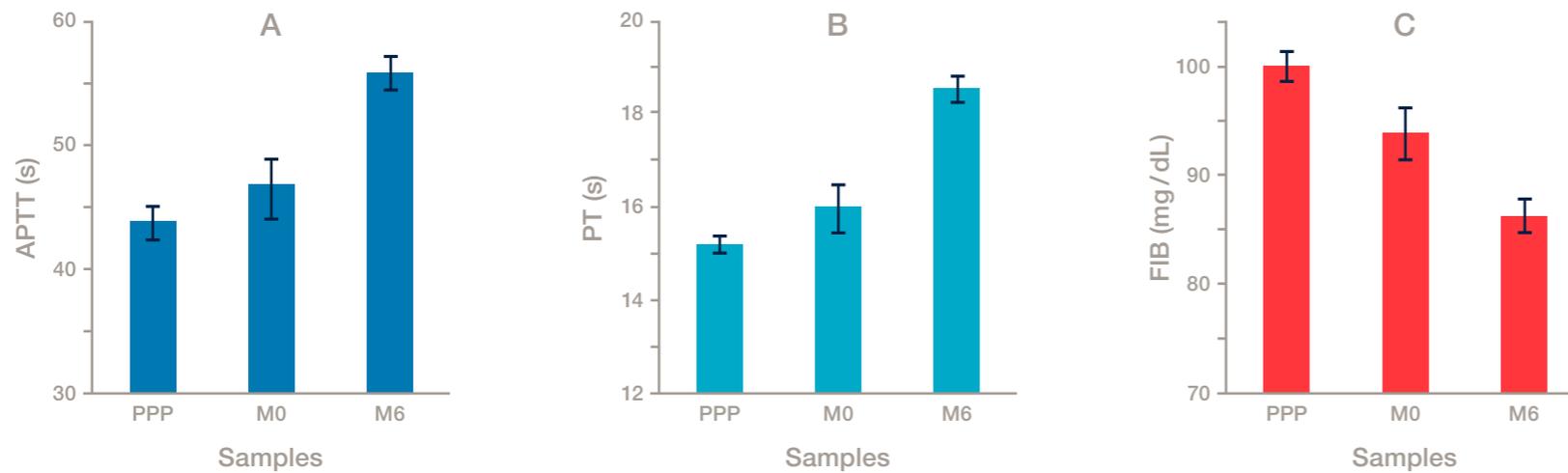


Figure 4. (A) Activated partial thromboplastin time (APTT), (B) prothrombin time (PT) and (C) the content of fibrinogen (FIB) transferring to fibrin of the PSf membranes.

Membrane	Anti-fouling ABSA ($\mu\text{g}/\text{cm}^2$)	Hemocompatibility APTT (s)
PSf/P(VP-VTEOS)	10.5 ± 0.4	55.6 ± 1.3
Pure PLA	~105	~45
PVA/PAN	28.9 ± 0.3	/
PES/PVP-f-MWCNT	~11.5	/

Figure 5. Comparison of the properties of M6 with some recently reported different membranes

Polysulfone hemodiafiltration membranes with enhanced anti-fouling and hemocompatibility modified by poly(vinyl pyrrolidone) via in situ cross-linked polymerization

Zhu L, et al. Mater Sci Eng C Mater Biol Appl. 2017 May 1;74:159-166

Conclusions

A simple in situ cross-linked polymerization method combined with NIPS enabled the fabrication of PSf membranes with enhanced surface hydrophilicity. The **modified membranes exhibited excellent antifouling performance and blood compatibility**, offering strong potential for clinical use in hemodiafiltration.



Comparison of efficacy and safety of the new generation helixone dialyzers

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Maduell F, et al. Nefrologia (Engl Ed). 2024 May-Jun;44(3):354-361

Comparison of efficacy and safety of the new generation helixone dialyzers

Maduell F, et al. Nefrologia (Engl Ed). 2024 May-Jun;44(3):354-361

Background

While PSU and PES dialyzers are effective for HD and HDF, a subset of patients experiences adverse reactions due to protein fouling and coagulation.

The new **FX CorAL**[™] helixone dialyzer incorporates PVP and α-tocopherol to strengthen the membrane's hydrophilic layer, improving antifouling and hemocompatibility.

Objective

This study evaluates the efficacy of the **FX CorAL**[™] helixone dialyzer in molecular clearance and the risk of albumin loss compared with earlier-generation dialyzers.

Comparison of efficacy and safety of the new generation helixone dialyzers

Maduell F, et al. Nefrologia (Engl Ed). 2024 May-Jun;44(3):354-361

Methodology

This prospective, single-centre study was carried out in 19 patients with a mean age of 74.7 ± 9.3 years, who were stable on a thrice-weekly hemodialysis programme for an average of 61 ± 80 months. Each patient underwent eight dialysis sessions in post-dilution HDF modality, with the following dialyzers: FX60 CorDiax, **FX CorAL** 60, FX600 CorDiax, **FX CorAL** 600, FX80 CorDiax, **FX CorAL** 80, FX800 CorDiax, and **FX CorAL** 800.

It investigated the intra-individual difference between the dialyzers regarding:

- **Performance** (GRS and RR of Urea, Creatinine, β 2M, Myoglobin, κ -FLC, λ -FLC, Prolactin, α 1M, α 1GP)
- **Albumin** (RR and Loss)

Results

- **Small-sized molecules:**
Similar dialysis dose as well as urea and creatinine RRs were observed across all dialyzers.
- **Medium-sized molecules:**
Removal of β 2-M, myoglobin, Λ -FLC, prolactin, α 1-M, and α 1-GP generally comparable across dialyzers, with FX80 CorDiax showing significantly higher clearance for several medium-sized molecules compared to other models.

Comparison of efficacy and safety of the new generation helixone dialyzers

Maduell F, et al. Nefrologia (Engl Ed). 2024 May-Jun;44(3):354-361

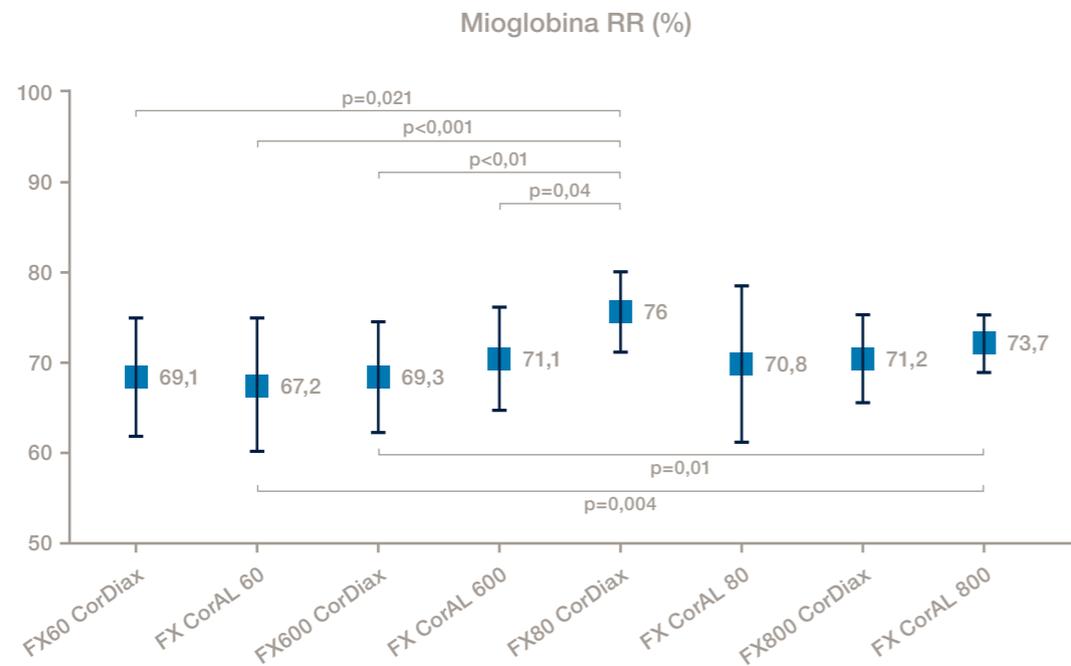


Figure 1. Comparison of myoglobin RRs in all study situations.

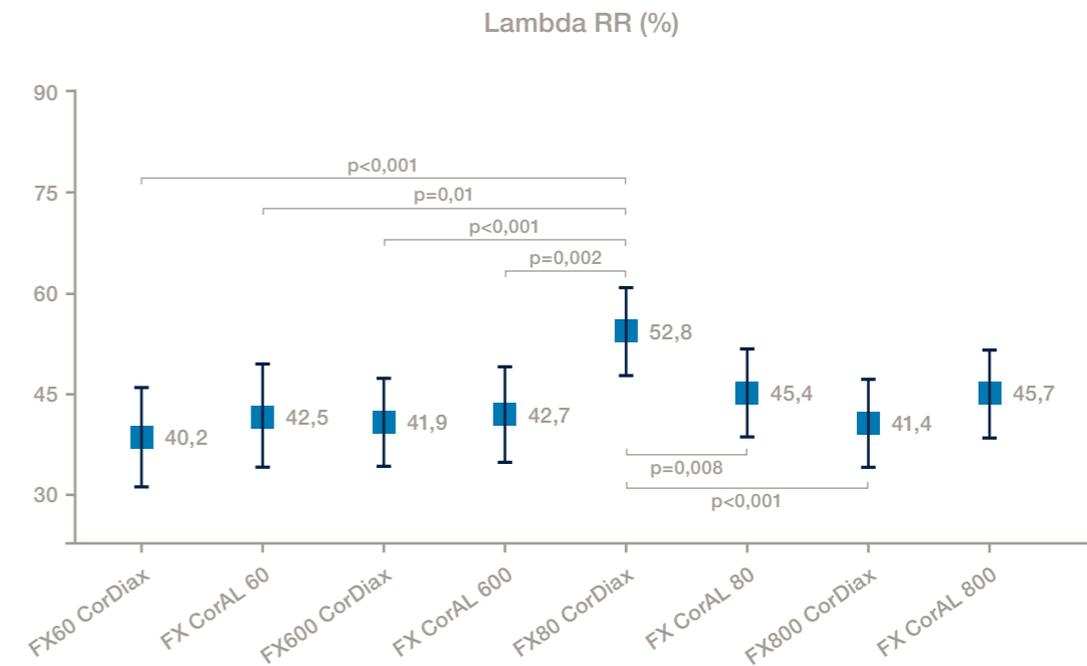


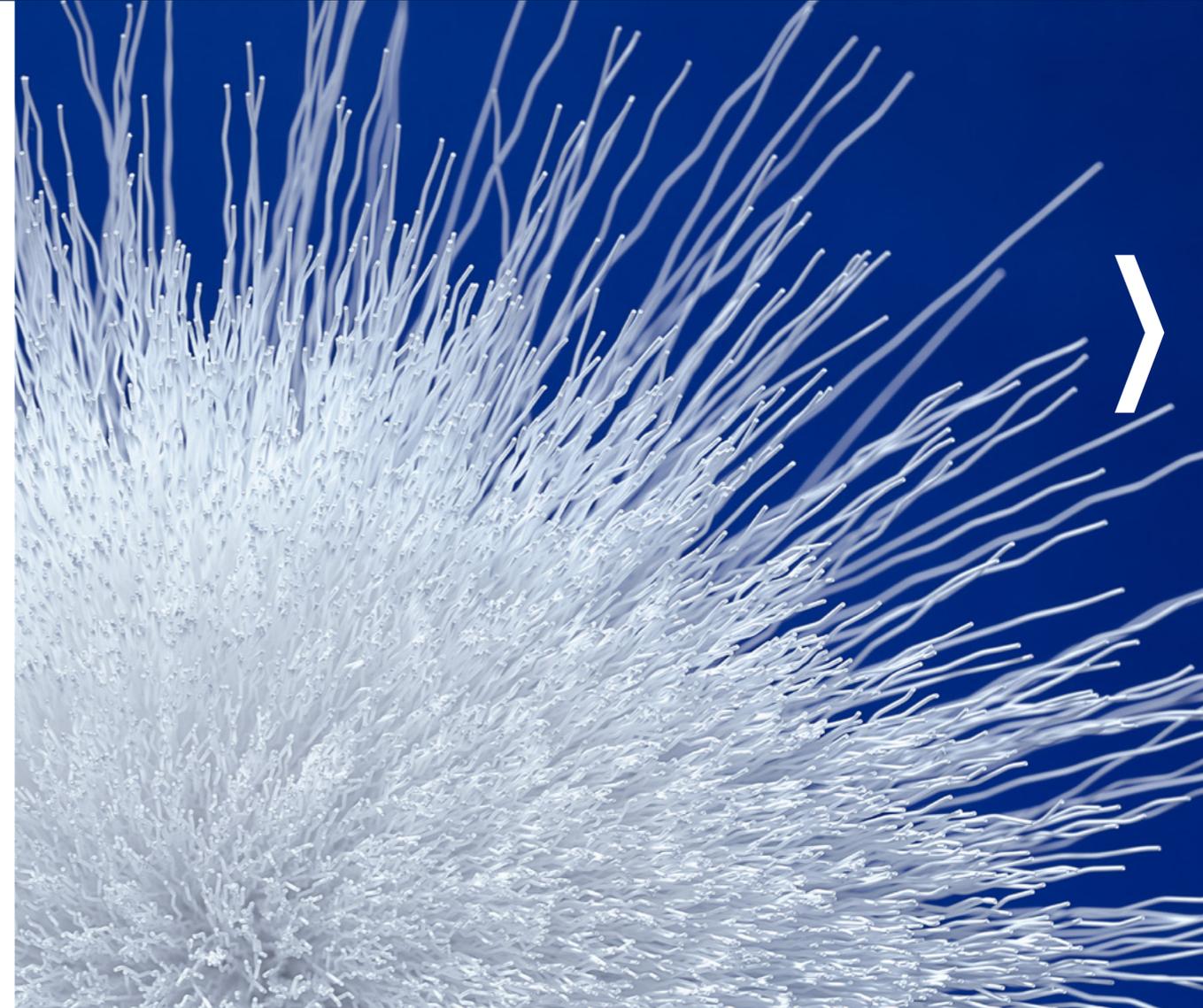
Figure 2. Comparison of lambda-free immunoglobulin light chains RRs in all study situations.

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Results

- **Albumin loss:**
Minimal across all dialyzers, with a mean amount of dialysate albumin loss <2.5 g across all study situations. Larger internal diameter dialyzers tended to show slightly lower albumin loss.
- **GRS:**
Average GRS values ranged from 55% to 60%, with FX80 CorDiax significantly outperforming other dialyzers, indicating superior overall solute clearance.



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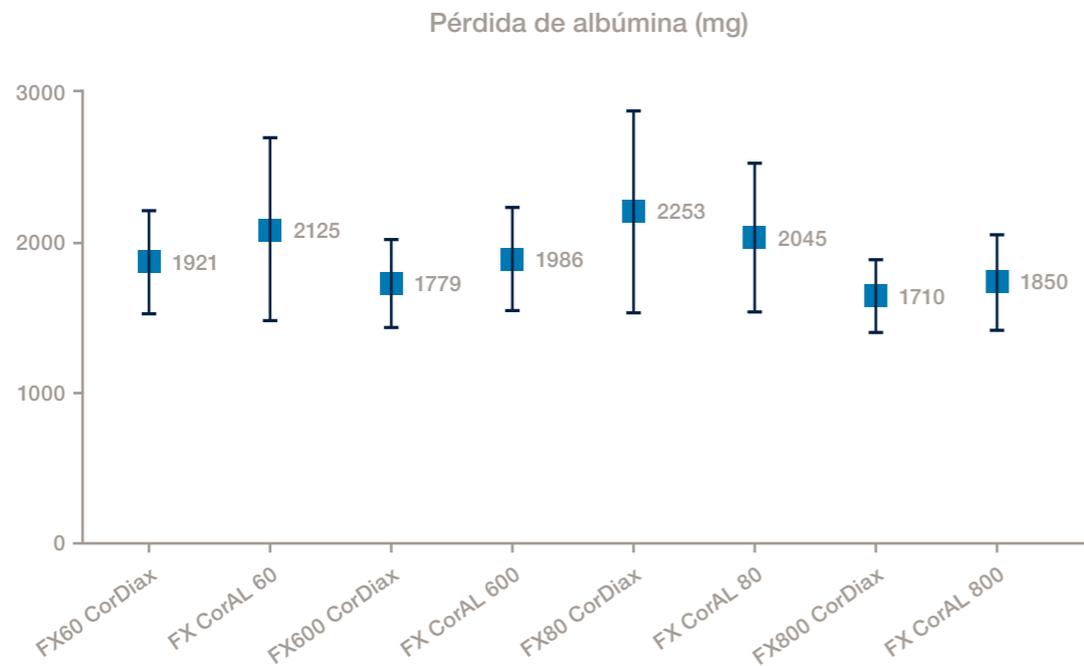


Figure 3. Comparison of dialysate albumin loss in all study situations.

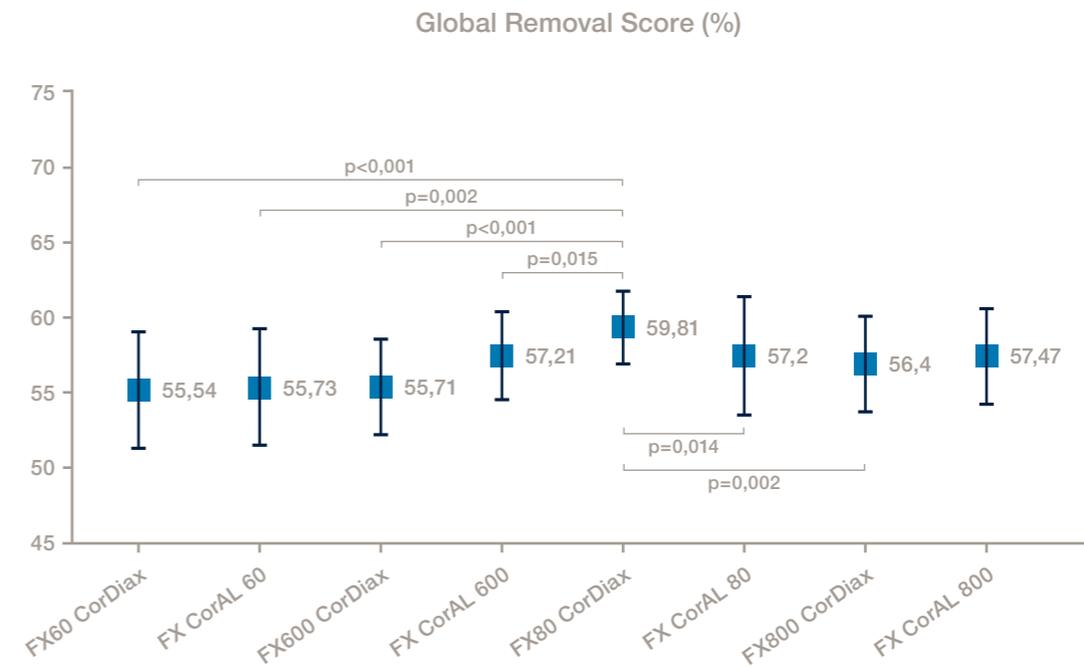


Figure 4. Comparison of global removal score in all study situations.

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Conclusions

New-generation helixone CorAL dialyzers incorporate PVP-stabilized polysulfone membranes to enhance blood compatibility. The modification helps maintain performance while potentially lowering the risk of adverse reactions.

Studies comparing different dialyzers remain therefore crucial for guiding nephrologists in device selection and treatment prescription.





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For more information about the new **FX CorAL
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