

CLINICAL EVALUATION OF NEW HIGH CUT OFF MEMBRANE

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INTRODUCTION

The uremic syndrome is characterized by the retention of various solutes that would normally be excreted by the kidney. Uremic toxins represent an heterogeneous group of substances that includes organic compounds and peptides both in their "native" and modified form, the latter by post-translational changes. Standard HD membranes are unable to depurate solutes with MW greater than 18 kDa. The aim of the study was to evaluate the performance of a new, more permeable dialytic membrane (Synclear 05) in terms of extraction capability of middle-high MW molecule. Synclear 05 is a new fiber used in the convective part of a double chamber filter in an HFR-like architecture therapy.

HFR is a form of Haemodiafiltration (HDF) that utilizes separately convection, diffusion and adsorption. A two-stages filter, consisting of a Synclear 02 (SUPRA) or Synclear 05 (KIDNEY) fiber (hyper permeability membranes with albumin sieving coefficient in water solution respectively of 0,2 and 0,5) in the 1st convective stage and a Low Flux polyethersulfone filter in the 2nd diffusive stage, is applied to enhance complete separation of convection from diffusion. The convective phase of the 1st stage extract pure ultrafiltrate (plasmatic water) that passes through a sorbent cartridge (SUPRASORB cartridge containing 80 ml of hydrophobic styrenic resin) that posses high affinity for several uremic toxins and middle molecules (Figure 1).

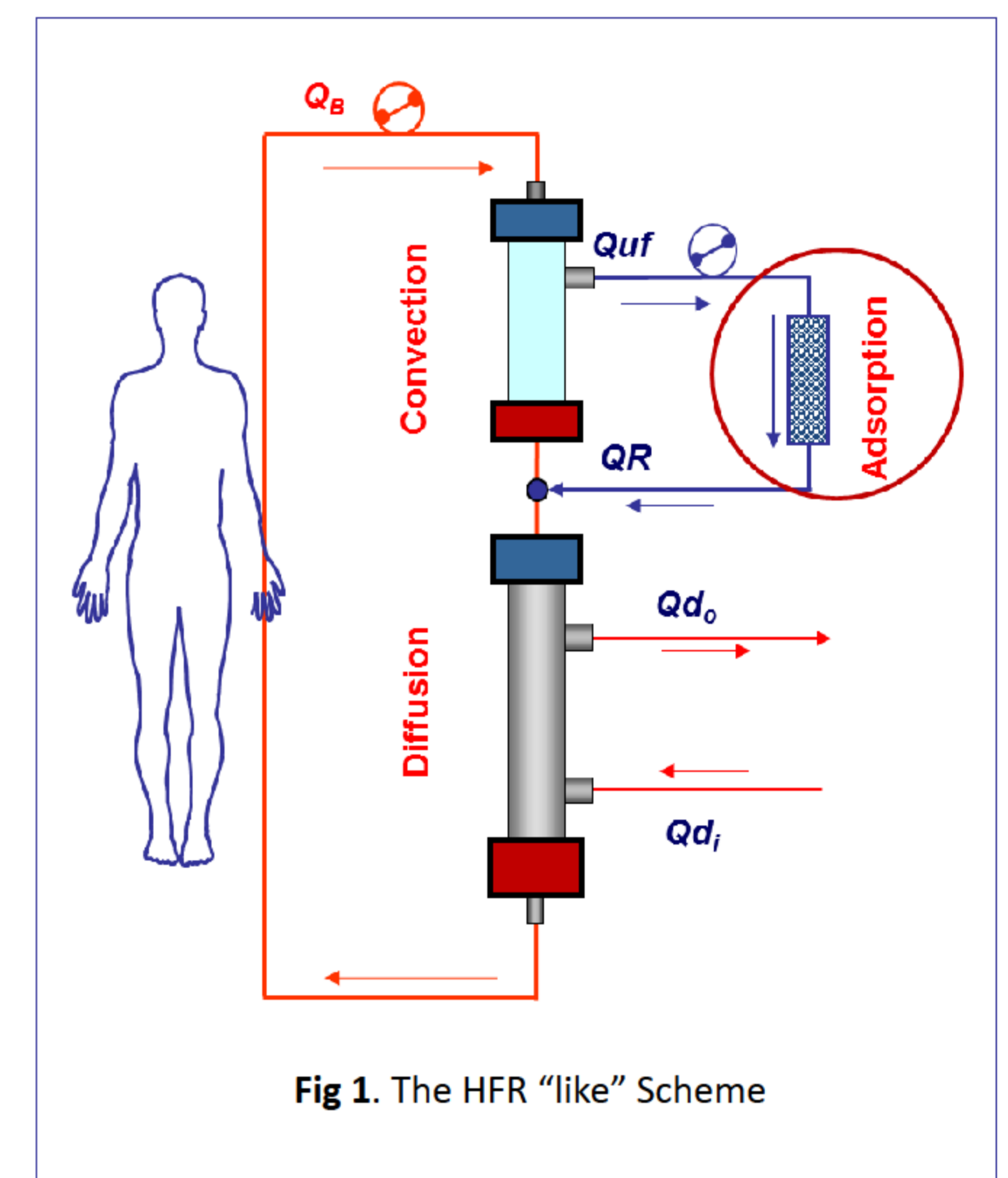
METHODS

Twenty ESRD patients (11 M), were enrolled for a prospective, crossover study in order to compare the extraction capability of two membranes used in SUPRA (Synclear 02) and KIDNEY (Synclear 05) therapies. After one week of washout stabilization period in standard bicarbonate dialysis (BD) for both Arm, the sequence of treatments was: one week of SUPRA, followed by one week of BD, followed by one week of KIDNEY treatment.

The mean age and the dialysis vintage of patients were respectively 72 15 years and 71 61 months. Treatments characteristics were: Q_b: (329 35) mL/min, Q_d: 500 mL/min for a treatment time of (232 19) minutes, in both techniques, three times a week.

Serum samples and pre-cartridge ultrafiltrate (UF) were collected at the beginning and at the end of each middle week session Plasma and UF samples were used to determine, β-2 microglobulin (β2M), free light chain (FLCs) κ and λ, Interleukin-6 (IL-6), α-1 acid glycoprotein (A1AG1), Albumin and Immunoglobulins G (IgG) levels.

β2M, FLC κ, FLC λ, A1AG1, Albumin and IgG were determined by nephelometric assays (BNII, Siemens Healthcare Diagnostics, Tarrytown, NY, USA); IL-6, were evaluated by Solid Phase Sandwich ELISA (Quantikine ELISA kit, R&D System, Minneapolis, MN, USA).



RESULTS

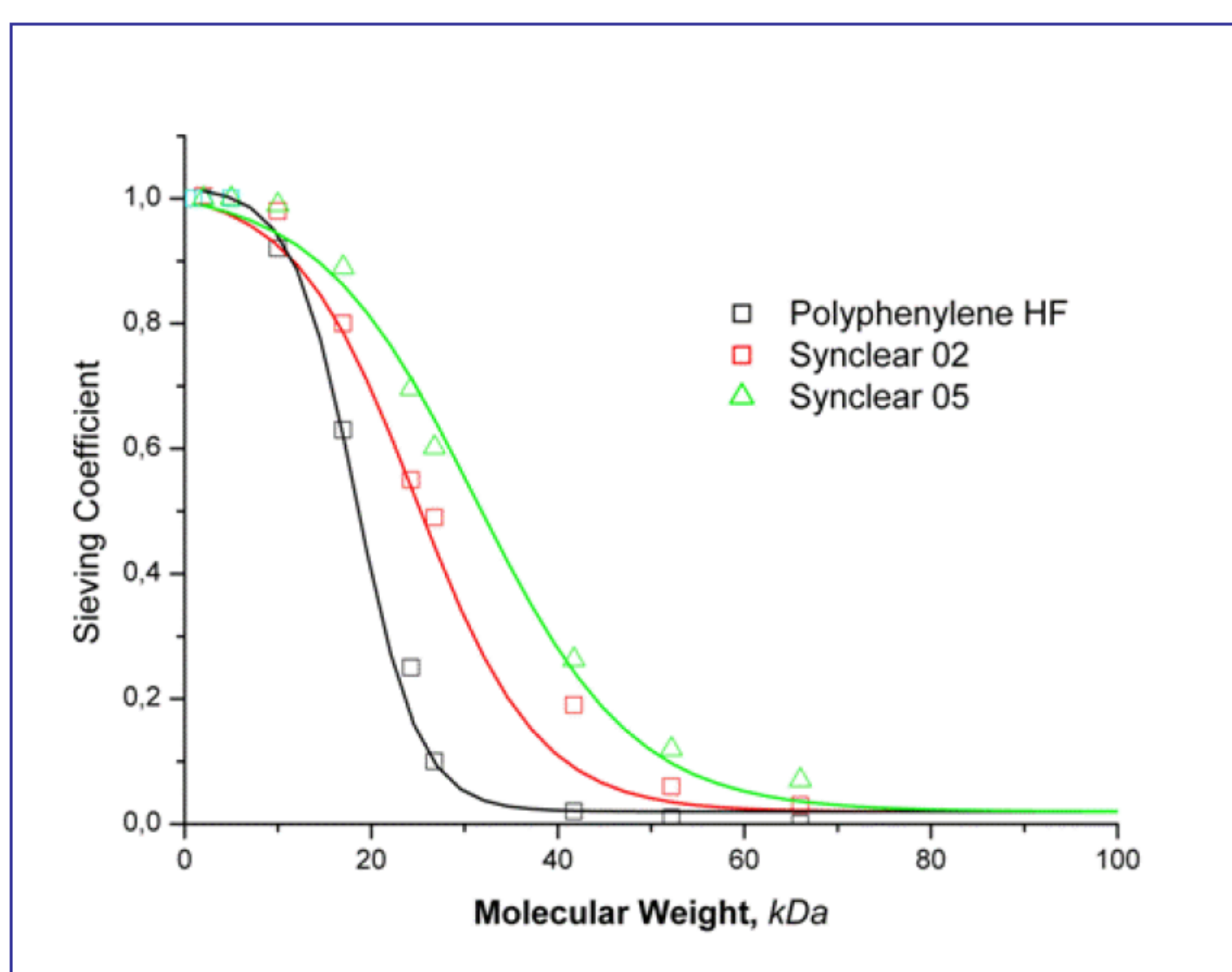


Fig 2: sieving curves of the two membranes calculated and compared with standard High Flux membrane

	MW (kDa)	Extraction (%)		p
		Sync 02	Sync 05	
β2M	12	68 ± 13	67 ± 12	ns
FLC κ	23	40 ± 11	65 ± 23	<0,0001
IL-6	24	49 ± 10	57 ± 12	<0,05
FLC λ	46	19 ± 5	28 ± 8	<0,0001
A1AG1	43	6 ± 2	12 ± 5	<0,0001
Albumin	66	3 ± 1	7 ± 3	<0,0001
IgG	150	0	2 ± 1	<0,0001

Table 1: Statistical differences between SUPRA and KIDNEY extraction capabilities.

Patients demographics and dialytic characteristics	
Gender:	11M – 9F
Age (yr):	71 ± 15
BMI (kg/m ²):	25 ± 4
Dialytic Vintage (mo):	71 ± 61
Body Weight (kg):	69,8 ± 15,0
Dialysis Time (min):	232 ± 19
Q _b (ml/min):	329 ± 35
Q _d (ml/min):	500

Table 2: Patients demographics and dialytic characteristics

Plasma and UF levels were evaluated both at the start and at the end of each treatment. Pre dialysis levels were not statistically different (data not shown). The extraction capability (expressed as percentage) was determined as ratio between UF and plasma concentrations both at the start and at the end of session and then averaged.

In order to compare the extraction capability and, consequently, the Molecular weight Cut off (MWCO) of the two membranes, a wide range of MW molecules were tested.

Statistically significant differences between SUPRA and KIDNEY extraction capabilities are shown in table 1. In figure 1 are reported the sieving curves of the two membranes calculated with the above data, compared with standard High Flux membrane

CONCLUSIONS

The results of this study demonstrate that, compared to SYNCLEAR 02, SYNCLEAR 05 membrane offers a higher permeability to middle MW molecules, and possess a MWCO higher than Sync 02 and other standard HDF membranes.

