TORAY

FILTRYZER® B1 SERIES

Hollow Fiber Dialyzer

PMMA for better quality of life

The PMMA membrane offers excellent clinical benefits to renal failure patients.

Biocompatibility

The PMMA membrane is a biocompatible membrane; no significant decrease in leukocyte (neutrophil) counts is observed during dialysis (Figure 1), complement activation is minimal (Figure 2).

Fig.1: Change in Neutrophil Counts during Dialysis [1]

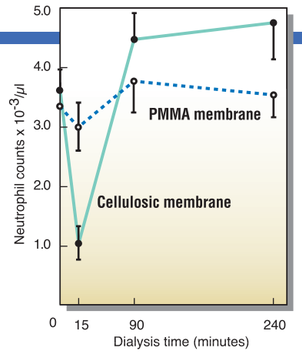
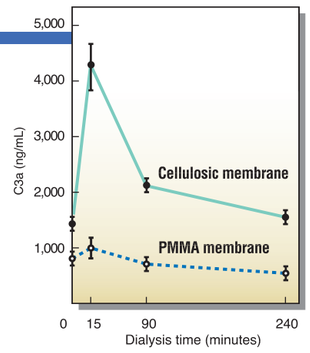


Fig.2: Change in C3a during Dialysis [1]



Application to patients with acute renal failure

Renal function in patients with acute renal failure (ARF) have faster recovery in dialysis with the PMMA membrane than with the cuprophane membrane (Figure 4).
Also a higher survival rate with the PMMA membrane has been reported (Figure 5).
These findings suggest that the highly biocompatible PMMA membrane facilitates recovery of renal function in ARF patients and contributes to their survival.

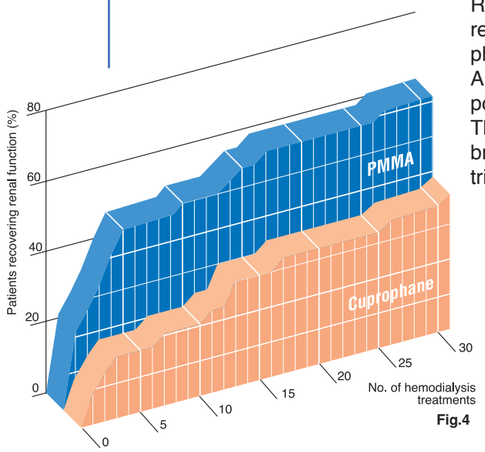


Fig.4

Fig.4: Recovery of renal function in patients with acute renal failure [3]

Figure 4: This figure shows the recovery of renal function in patients with acute renal failure undergoing dialysis with the polymethylmethacrylate or cuprophane membrane, according to the number of hemodialysis treatments.
Not shown on the graph are the results for one patient in the group undergoing dialysis with the polymethylmethacrylate membrane, who recovered renal function after 72 treatments.

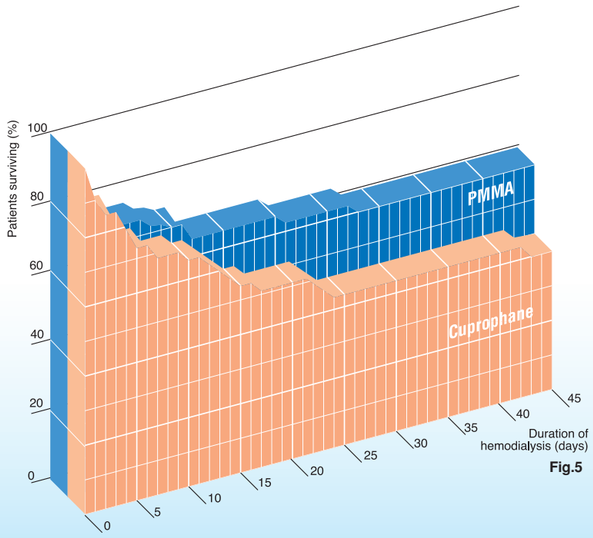


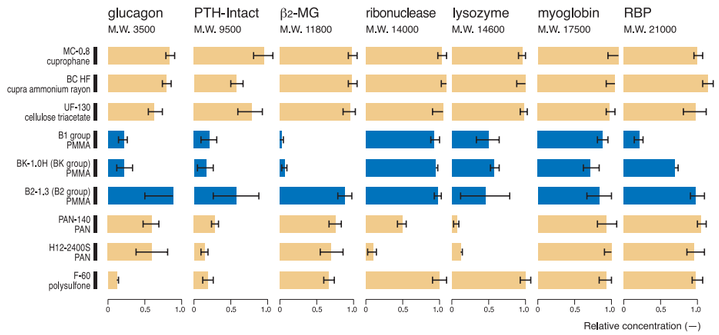
Fig.5

Fig.5: Survival of patients with acute renal failure [3]

Figure 5: This figure shows the survival of patients with acute renal failure undergoing dialysis with the polymethylmethacrylate or cuprophane membrane.
Not shown on the graph are the results for one patient in the group undergoing dialysis with the polymethylmethacrylate membrane, who died after 81 days, and one patient in the group undergoing dialysis with the cuprophane membrane, who died after 61 days.

Adsorption of β_2-MG and other proteins

Fig.3: Relative concentrations of low molecular weight proteins after contacting with membranes for 3hrs [2]

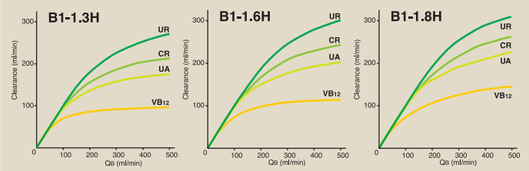


Though the PMMA membrane (B1 Group) has a low sieving coefficient (SC) for beta 2 microglobulin (β_2-MG) and the amount of β_2-MG in dialysate is minimal, the β_2-MG concentration in patients' plasma has significantly been lowered by using the PMMA membrane.
As shown in Figure 3, removal of proteins such as β_2-MG has efficiently been achieved by adsorption to the PMMA membrane.

Technical Data; B1 Series Filtryzer

Type			B1-1.3H	B1-1.6H	B1-1.8H	B1-2.1H
Housing	Material		Polystyrene			
	Length (mm)		283			
	Diameter (mm)		41	45	45	53
Weight (filled) (g)			420	520	520	650
Blood volume (mL)			76	95	105	126
Filled fluid			Sterile water			
Fibers	Material		Polymethylmethacrylate (PMMA)			
	Quantity		10,900	13,300	14,700	17,100
	Inside diameter (μm)		200			
	Membrane thickness (μm)		20			
	Effective surface area (m^2)		1.3	1.6	1.8	2.1
	Effective length (mm)		195			
Potting	Material		Polyurethane			
Sterilization			Gamma-ray irradiation			
Maximum transmembrane pressure {kPa (mmHg)}			66 (500)			
Clearance in vitro (mL/min)*						
	Urea	designed	180	187	191	195
		not less than	170	177	181	185
	Creatinine	designed	156	167	175	183
	Uric acid	designed	138	150	160	170
	Phosphate	designed	140	155	163	172
	Vitamin B_{12}	designed	86	98	109	120
UFR in vitro {mL/hr, at 13.3kPa (100mmHg)}**			1,200	1,400	1,600	1,800

Clearance



B1-1.3H (Q_D: 500ml/ min, TMP: 100mmHg, Qf: 29ml/ min)

Q_B	100	200	300	400	500
Urea	100	180	226	253	271
Creatinine	97	156	186	203	213
Uric acid	93	138	156	169	175
Vitamin B_{12}	70	86	90	93	95

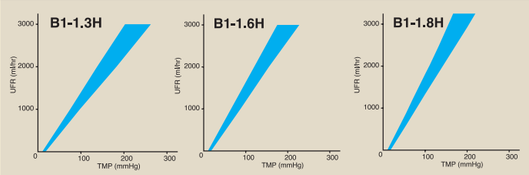
B1-1.6H (Q_D: 500ml/ min, TMP: 100mmHg, Qf: 36ml/ min)

Q_B	100	200	300	400	500
Urea	100	187	245	279	301
Creatinine	99	167	208	229	243
Uric acid	97	150	179	194	203
Vitamin B_{12}	79	98	108	112	114

B1-1.8H (Q_D: 500ml/ min, TMP: 100mmHg, Qf: 36ml/ min)

Q_B	100	200	300	400	500
Urea	100	191	253	291	316
Creatinine	99	175	219	245	262
Uric acid	97	160	193	211	223
Vitamin B_{12}	81	109	121	128	132

UFR **



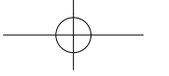
* Clearances are data with aqueous solution.
Q_B: 200 ±4mL/min, Q_D: 500 ±10mL/min, TMP: 13.3 ±1.3kPa (100 ±10mmHg), Temp.: 37 ±1°C
** UFR is typical data with bovine blood. (Ht 30 ±3%, TP 6 ±0.5g/dL)
Q_B: 200 ±4mL/min, TMP: 13.3 ±1.3kPa (100 ±10mmHg), Temp.: 37 ±1°C
Allowable ranges :
Blood volume: ±13%, Designed clearance: Urea upper limit: +6%, Lower limit: see above, Creat: ±6%, Others: ±13%, UFR in vitro: ±15%

REFERENCES

1) From Hakim RM, et al. Biocompatibility of dialysis membranes: Effects of chronic complement activation. Kidney International 1984; 26: 194-200.
2) Suzuki M. Recent advances of high performance membranes for hemodialysis. MEMBRANE. 1992; 17: 1: 3-11.
3) Hakim RM. Effect of the dialysis membrane in the treatment of patients with acute renal failure. The New England Journal of Medicine 1994; 17: 1338-1342.

INSTRUCTIONS

Filtryzer B1 series is medical devices intended for hemodialysis (HD).
These devices must be used by or at the direction of a physician.
Patients with bleeding tendencies or coagulation disorders must be carefully evaluated by the physician.
When adverse reactions are observed, the patients must be promptly treated under the direction of the physician. For some reactions, manipulation of blood flow rate, ultrafiltration rate, and electrolytic balance can be applied.
The "Instructions for Use" should be read thoroughly prior to the use of the devices.
Each unit is carefully tested, sterilized and packaged prior to shipment. Toray cannot assume any responsibility for damage that may occur during transport or due to mishandling.
Filtryzers are filled with sterile water. Prior to dialysis,rinse with one liter or more of physiological saline solution.
Filtryzers are designed and manufactured for single use only.
Since Filtryzer B1series has high ultrafiltration rates, it is necessary to use dialysis machines equipped with a volumetric ultrafiltration rate controller.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