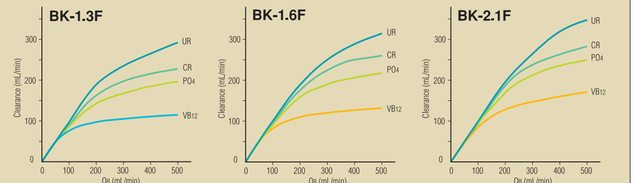
Technical Data; BK-F series Filtryzer

Type			BK-1.3F	BK-1.6F	BK-2.1F
Housing	Material			Polystyrene	
Fibers	Material			Polymethylmethacrylate	
	Inner diameter (μm)			200	
	Membrane thickness (μm)			30	
	Effective surface area (m^2)		1.3	1.6	2.1
Potting Material				Polyurethane	
Sterilization				Gamma-ray Irradiation	
Blood Volume (mL)			76	94	126
Clearance *in vitro* (mL/min)*					
	Urea	designed	183	190	195
	Creatinine	designed	160	172	181
	Phosphate	designed	144	157	171
	Vitamin B_{12}	designed	99	111	128
	Inulin	designed	53	61	73
UFR *in vitro* {mL/hr, at 13.3kPa (100mmHg) }**			1,600	2,000	2,600
Max. TMP {kPa (mmHg) }				66 (500)	

* Clearances are data with aqueous solution
Qʙ: 200 ±4mL/min, Qᴅ: 500 ±10mL/min, Qꜰ: 10 ±2 mL/min, Temp.: 37 ±1°C
** UFRs are typical data with bovine blood. (Ht 30 ±3%, TP 6 ±0.5g/dL)
Qʙ: 200 ±4mL/min, TMP: 13.3 ±1.3kPa (100 ±10mmHg), Temp.: 37 ±1°C

Clearance

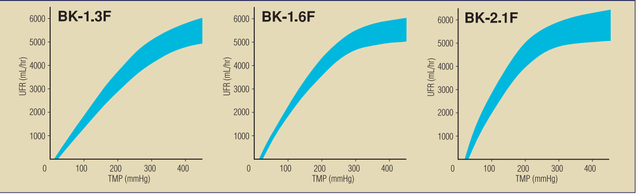


Qʙ	100	200	300	400	500
UR; Urea	100	183	235	266	286
CR; Creatinine	97	160	194	214	226
PO_4; Phosphate	94	144	169	182	191
VB_{12}; Vitamin B_{12}	76	99	108	113	116

Qʙ	100	200	300	400	500
UR; Urea	100	190	250	288	312
CR; Creatinine	99	172	213	237	252
PO_4; Phosphate	96	157	187	204	216
VB_{12}; Vitamin B_{12}	82	111	124	131	135

Qʙ	100	200	300	400	500
UR; Urea	100	195	268	314	344
CR; Creatinine	100	181	236	267	287
PO_4; Phosphate	99	171	210	234	249
VB_{12}; Vitamin B_{12}	89	128	147	157	163

UFR



"TORAY"

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"TORAY"

FILTRYZER® BK-F SERIES

Hollow Fiber Dialyzer

PMMA for better quality of life

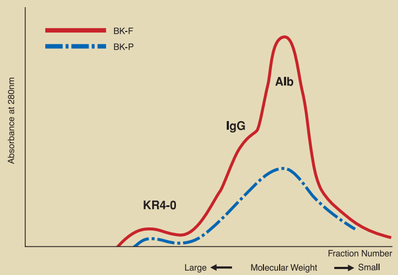
The PMMA membrane offers excellent clinical benefits to renal failure patients.

PMMA Membrane; More Efficient for the Elimination of Large Molecular Weight Substances.

It is suggested that pathogenic substances, such as erythropoiesis inhibitory factors[1-6, 7], substances related to bone disease[8], immunosuppressive factors[9] etc, exist in the large molecular weight range from 50,000 to 1,000,000 daltons. The large molecular weight substances, however, are not removed in conventional HD treatment so as not to lose excessive albumin.

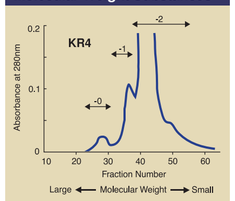
With that in mind, Toray developed the BK-F series to have a larger pore size than the conventional BK-U and -P series and it is expected to remove larger molecular weight substances than albumin.

Gel Filtration Chromatography Pattern of Concentrated Dialysate Obtained Using BK-F and BK-P [7]



BK-F can remove larger molecular weight substances than BK-P.

BK-F Removes Large Molecular Weight Substances[7]

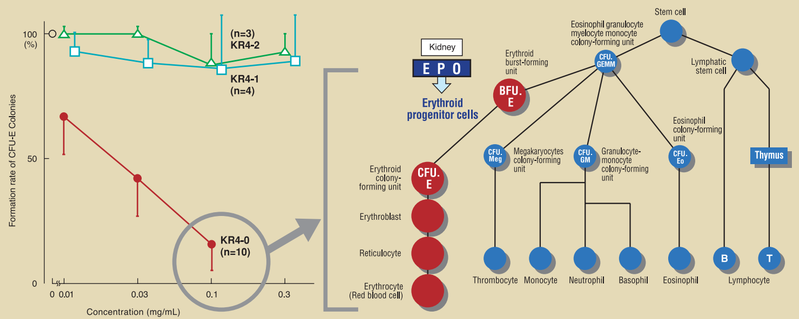


Concentrated dialysate of chronic renal failure (CRF) patients who were dailyzed with the new BK-F membrane was fractionated with a Sephacryl gel column.

Substances in the concentrated filtrate were separated by molecular weight into three fractions called KR4-0, KR4-1, and KR4-2.

Fractions of KR4-1 and 4-2 primarily consist of IgG and albumin, respectively. KR4-0 fraction whose estimated molecular weight was between 500,000 and 1,000,000 daltons was found mainly in the dialysate when BK-F membrane was employed.

An Inhibitor of Erythropoiesis Exists in Large Molecular Weight Substances?



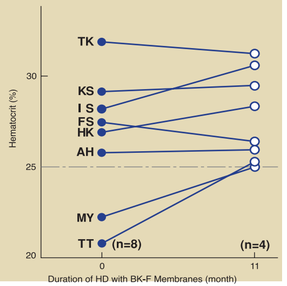
Inhibition of CFU-E Colonies Formation by Each Fraction [7]

KR4-0, large molecular weight substances, had an inhibitory effect on the formation of mice bone marrow erythroid. progenitor cells (CFU-E), while KR4-1 and 4-2 did not, and its inhibitory activity was promoted as its concentration increased.

This illustrates how erythropoiesis is inhibited by such large weight molecules as KR4-0 fraction.

The formation of CFU-E colonies is inhibited by KR4-0 fraction in the process of forming red blood cells.

Hematocrit Change Using BK-F Membrane [7]



A clinical study using BK-F hemodialyzers was performed on 8 CRF patients without administering erythropoietin (EPO). As illustrated above, 6 out of 8 CRF patients maintained hematocrit (Hct) at an acceptable level (25-30%) for 11 months, and 2 out of 8 patients, who had extremely low Hct before the study, showed improvement in Hct from 21-22% to 25% after 11months.

Minimized Loss of Total Protein [7]

	Control	Duration of Dialysis using BK-F	
		3~5 Months	8~10 Months
Albumin	3.8 ± 0.2 (16)	3.7 ± 0.3 (24)	3.7 ± 0.3 (24)
		NS	
		NS	
IgG	1340 ± 347 (8)	1393 ± 385 (8)	1325 ± 360 (8)
		NS	
		NS	
IgA	114.5 ± 84.2 (8)	135.9 ± 96.7 (8)	120.9 ± 84.3 (8)
		NS	
		NS	
IgM	102.3 ± 50.7 (8)	111.0 ± 57.0 (8)	100.5 ± 47.7 (8)
		NS	
		NS	
Total Cholesterol	159.2 ± 25.5 (8)	190.8 ± 31.5 (24)	181.2 ± 31.5 (16)
		p<0.05	
		NS	

Even though large molecular weight substances can be removed, the sieving coefficient for albumin is only about 0.03.

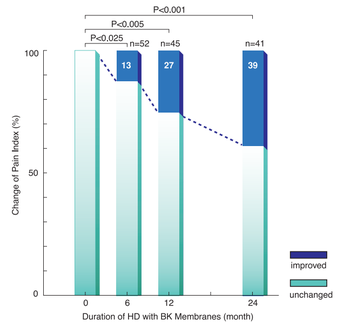
As illustrated above (mean ±SD (n)), the elution of albumin, IgG, IgA, and IgM were studied. No significant changes were obtained during 10 months using BK-F in the HD mode.

Long-term Multicenter Clinical Evaluation

BK-F dialyzers remove β_2-microglobulin, which is considered to be one of the pathogenic substances of amyloidosis, as our conventional BK-U and -P series can.

It has been reported in the long-term multicenter studies both at home and abroad with the BK series that it is effective in preventing carpal tunnel syndrome (CTS) in long-term dialysis patients and in improving itching[11], joint pain, bone cysts[10], etc.

Time Course of Changes of Pain Index during BK Membrane Hemodialysis[11]



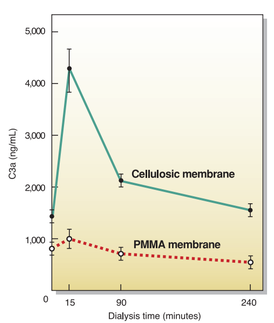
Biocompatibility

Polymethylmethacrylate (PMMA) membranes are less complement activating, have less reduction in neutrophil counts, and do little damage to platelets[12] during dialysis, because of its superior biocompatibility.

In clinical use of PMMA membrane, the plasma levels of cytokines, such as TNF-α and IL-1β were consistently reduced in respect to the predialytic values relative to other membranes[9].

Thanks to gamma-ray sterilization, there is no concern about side effects due to residual sterilants.

Change of C3a During Dialysis[9]



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INSTRUCTIONS:

Filtryzer BK-F series is a medical device intended for hemodialysis (HD), but must not be used for HDF (hemodiafiltration) or HF (hemofiltration) due to the higher permeability of larger molecular weight proteins such as albumin.

This device 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 this medical device.

Filtryzer is manufactured in accordance with "Approval Standard of Artificial Kidney" by the Ministry of Health, Labour and Walfare of Japanese Government.

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.

Filtryzer is filled with sterile water. Before starting dialysis, rinse it out with one liter or more of physiological saline solution.

Since Filtryzer BK-F series has high ultrafiltration rates, it is necessary to use a dialysis machine equipped with a volumetric ultrafiltration rate controller.