'TORAY'

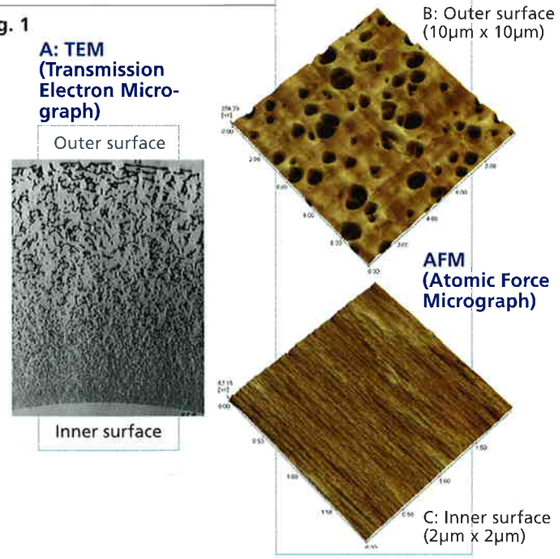
Hollow Fiber Dialyzer

Toraysulfone TS-S/U SERIES

Toraysulfone—Excellent Polysulfone Membran

Optimum Membrane Structure by Advanced Nano-Technology

Fig. 1



Sharp Molecular Weight Cut-off

Polysulfone membrane has an asymmetric membrane structure with high solute removability and ultrafiltration.

Fig. 1 shows, A: TEM observation on membrane section, B and C: AFM observation on membrane surface. All of them show the asymmetric pore structure of the membrane.

Table 1 is a comparison of each polysulfone membrane structure by nanoscopic characterization using Atomic Force Microscope.

The result suggests that Toray Toraysulfone has the following characteristics compared to other polysulfone membranes.

1. Substances can pass easily through the membrane because of its thin skin layer, small tortuosity and short pore length.
2. Larger molecular weight substances such as albumin do not easily pass through Toraysulfone membrane because of its low water content and small pore at skin layer.

Toray polysulfone "Toraysulfone" has an optimal membrane structure among high-flux polysulfone membranes.

Table 1

Membrane	Water content (%) Skin layer	Water content (%) Support layer	Tortuosity Skin layer	Tortuosity Support layer	Thickness (μm) Skin layer	Thickness (μm) Support layer	Pore diameter (nm) Skin layer	Pore diameter (nm) Support layer	Pore length (μm)
Toraysulfone	27	70	1.13	1	2	38	8.8	418	40.3
A1	31	70	1.73	1	3	42	11	494	47.2
A2	42	73	1.14	1	7	38	9.5	499	46.0
A3	47	77	1.80	1	2	38	13.0	699	41.6

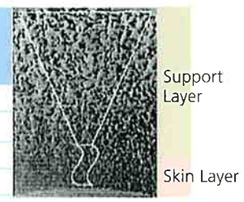
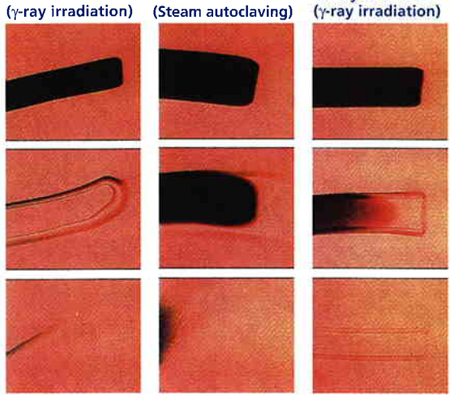


Fig. 2



Crosslinked Structure of PVP in Toraysulfone Membrane

Polyvinylpyrrolidone (PVP) in Toraysulfone membrane is crosslinked during γ-ray sterilization, and less PVP is eluted from membrane.

Fig. 2 is an observation of three different polysulfone membranes after soaking in DMAc (solvent for polysulfone).

PVP dissolves away together with polysulfone in A2 and A3 membrane. However crosslinked PVP in Toraysulfone remains as a transparent structure.

Crosslinked PVP in Toraysulfone remains even in the solvent.

Toraysulfone has less elution of PVP compared to other membranes.

Spacer Yarns

Toraysulfone hollow fibers are covered by "Spacer yarns" as shown in Fig. 3.

Spacer yarns facilitate the dialysate to flow uniformly around the hollow fibers and to reduce the "mass transfer resistance in dialysate side" without affecting a pressure drop in the dialysate compartment.

Spacer yarns help to enhance the efficiency of dialysis.

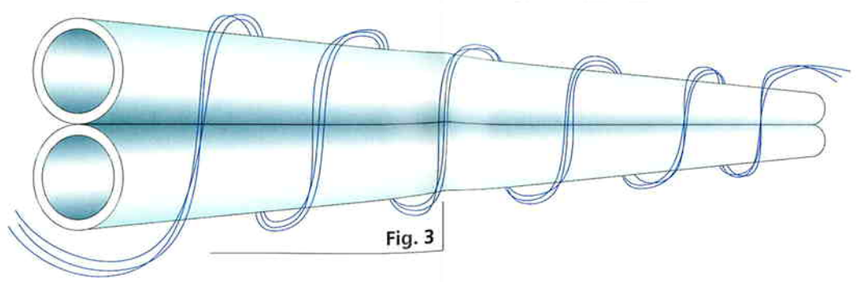


Fig. 3

New design

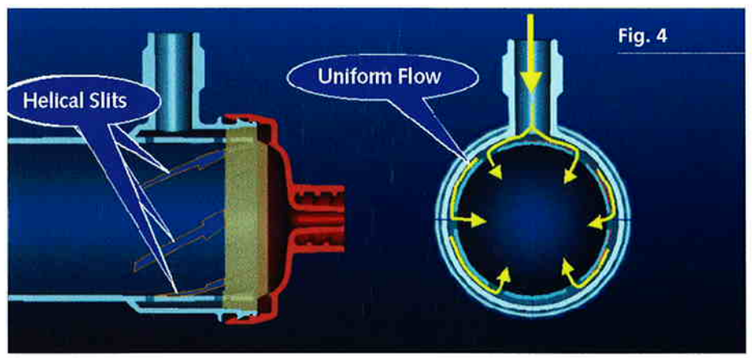
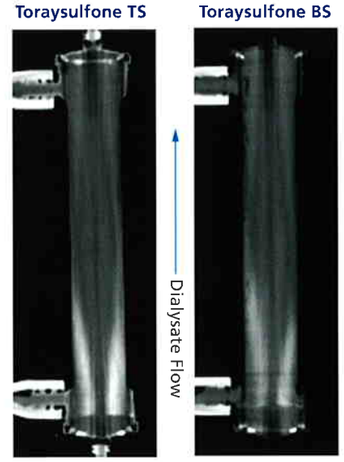


Fig. 4

Fig. 5



Helical Slits Structure

Toraysulfone TS series has specially designed baffle structure with helical slits, in order to obtain the uniform flow of dialysate. (Fig. 4)

In this new design, the baffle was arranged so as to surround both ends of the fiber bundle. The dialysate uniformly penetrates into the fiber bundle from surrounding slits.

Uniformity of dialysate flow in the new Toraysulfone TS series can be observed by X-ray CT scan as shown in Fig. 5.

e—

perior Performance and Proven Biocompatibility

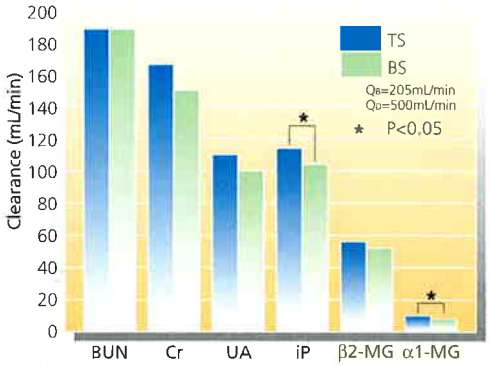
al Evaluation of Clearance

arances of new Toraysulfone TS series and BS series (cur-oduct) were compared in 8 end stage renal disease (ESRD) s (crossover study).

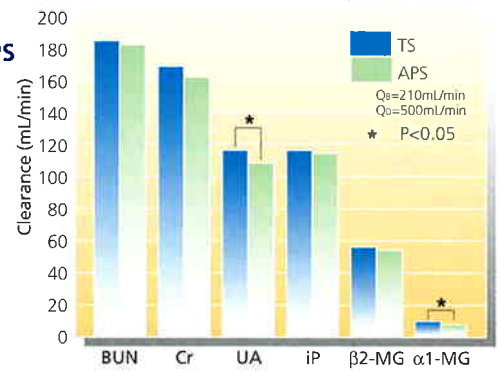
arances of phosphate and α1-MG in TS series were signifi-higher than BS series. (Fig. 6)

omparison of clearances in 6 ESRD patients (crossover between TS series and another polysulfone dialyzer (APS), nces in uric acid and α1-MG were also significantly higher ysulfone TS series. (Fig. 7)

Comparison of nce in TS and BS



Comparison of nce in TS and APS



Comparison of Biocompatibility

Significant change in C3a and leukocyte counts were observed with FB (CTA membrane). In contrast, less significant changes were observed with Toraysulfone membrane. This suggests that the Toraysulfone membrane has better biocompatibility than that of FB. (Fig. 8, 9)

Fig. 8: Changes in C3a comparing Toraysulfone and FB

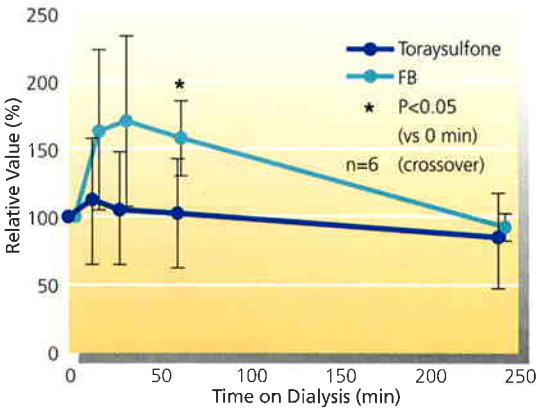
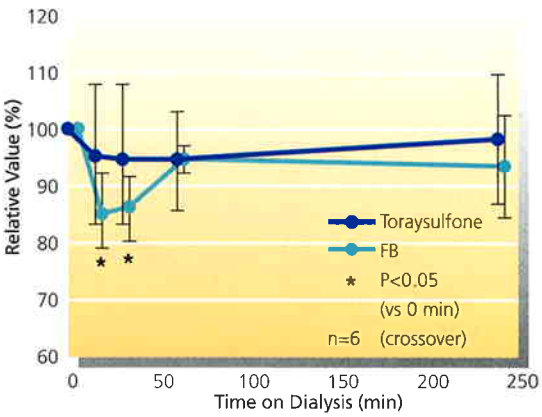


Fig. 9: Changes in leukocyte counts comparing Toraysulfone and FB



Technical Specifications and Data

Type		TS-1.3S	TS-1.6SL	TS-1.8SL	TS-2.1SL	TS-1.3U	TS-1.6UL	TS-1.8UL	TS-2.1UL
Housing	Material	Polycarbonate							
Fibers	Material	Polysulfone							
	Inner diameter (μm)	200							
	Membrane thickness (μm)	40							
	Effective surface area (m^2)	1.3	1.6	1.8	2.1	1.3	1.6	1.8	2.1
Potting Material		Polyurethane							
Sterilization		Gamma-ray Irradiation							
Blood Volume (mL)		84	95	105	124	85	95	108	125
Clearance in vitro (mL/min)*									
	Urea	193	195	198	198	193	196	198	199
	Creatinine	187	193	195	195	185	192	196	197
	Phosphate	179	192	194	195	180	193	196	196
	Vitamin B_{12}	140	156	164	168	140	162	167	171
	Inulin	104	124	129	138	110	131	140	142
UFR in vitro {mL/hr, at 13.3kPa (100mmHg)}**		4,400	4,900	5,000	5,200	4,300	4,900	5,100	5,500
Max. TMP {kPa (mmHg)}		66 (500)							

* *Clearances are measured with aqueous solution. Q_B: 200 ±4mL/min, Q_D: 500 ±10mL/min, Q_F: 10mL/min, Temp.: 37 ±1°C*

** *UFRs are measured data with bovine blood. (Ht 30 ±2%, TP 6g/dL) Q_B: 200mL/min, TMP: 13.3kPa (100mmHg), Temp.: 37°C*

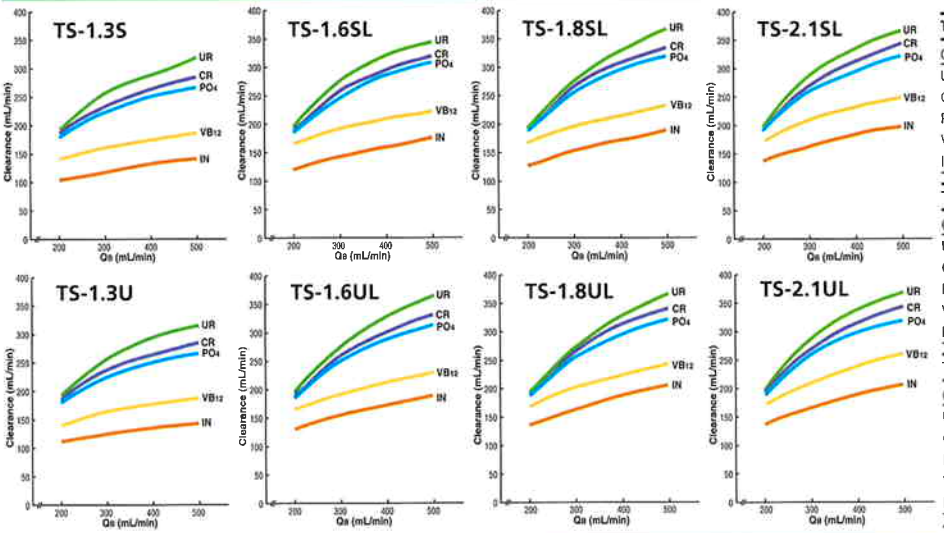
Allowable ranges

Blood volume; ±13%. Clearances, Urea & Creatinine; ±6%, Phosphate & Vitamin B_{12}; ±13%, UFR in vitro; ±15%

"Instructions for Use" should be read thoroughly prior to the use of these medical devices.

Specifications and designs are subject to change without notice for improvements.

Clearance



TS-1.3S				
Q_B	200	300	400	500
UR; Urea	193	255	289	320
CR; Creatinine	187	235	260	285
PO_4; Phosphate	179	223	250	268
VB_{12}; Vitamin B_{12}	140	161	172	187
IN; Inulin	104	117	131	140

TS-1.3U				
Q_B	200	300	400	500
UR; Urea	193	257	294	323
CR; Creatinine	185	238	264	285
PO_4; Phosphate	180	224	250	268
VB_{12}; Vitamin B_{12}	140	164	178	187
IN; Inulin	110	123	135	143

TS-1.6SL				
Q_B	200	300	400	500
UR; Urea	195	271	320	348
CR; Creatinine	193	255	293	315
PO_4; Phosphate	192	248	283	307
VB_{12}; Vitamin B_{12}	156	187	207	221
IN; Inulin	124	142	156	175

TS-1.6UL				
Q_B	200	300	400	500
UR; Urea	196	274	326	358
CR; Creatinine	192	259	301	327
PO_4; Phosphate	193	250	287	311
VB_{12}; Vitamin B_{12}	162	194	216	232
IN; Inulin	131	152	170	184

TS-1.8SL				
Q_B	200	300	400	500
UR; Urea	198	275	332	363
CR; Creatinine	195	262	306	333
PO_4; Phosphate	194	254	292	317
VB_{12}; Vitamin B_{12}	164	197	218	234
IN; Inulin	129	153	165	182

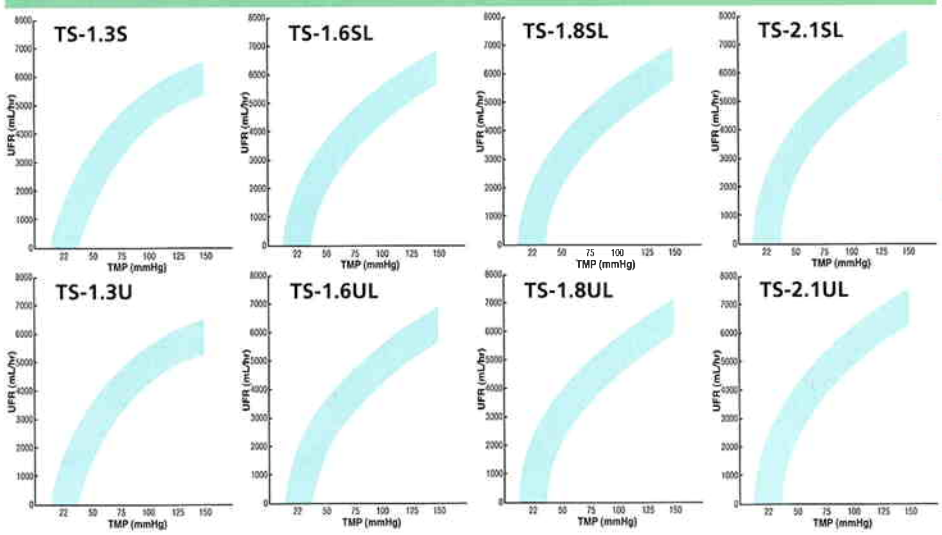
TS-1.8UL				
Q_B	200	300	400	500
UR; Urea	198	277	332	367
CR; Creatinine	196	264	308	340
PO_4; Phosphate	196	258	297	324
VB_{12}; Vitamin B_{12}	167	202	226	248
IN; Inulin	140	162	182	202

TS-2.1SL				
Q_B	200	300	400	500
UR; Urea	198	279	335	369
CR; Creatinine	195	268	313	342
PO_4; Phosphate	195	258	296	321
VB_{12}; Vitamin B_{12}	168	204	230	249
IN; Inulin	138	160	180	196

TS-2.1UL				
Q_B	200	300	400	500
UR; Urea	199	280	336	371
CR; Creatinine	197	268	314	344
PO_4; Phosphate	196	259	299	326
VB_{12}; Vitamin B_{12}	171	207	235	253
IN; Inulin	142	166	185	204

Measured data with aqueous solution

UFR



References

1) *Sakai, K., taken from the presentation made at the 48th Annual Meeting of the Japanese Society for Dialysis Therapy, Jun. 2003 (Fig.1, Table 1)*

2) *Hayama, M., Yamamoto, K., Kohori, F., Sakai K., et al., Biomaterials 25 (2004) 1019-1028 (Fig.1, Table 1)*

3) *Sakai, Y., et al., taken from the presentation made at the 22nd Annual Meeting of ISBP, Sep. 2004 (Fig. 5)*

4) *Miyaji, H., et al., taken from the presentation made at the 20th Annual Meeting of HPM, Mar. 2004 (Fig. 6, 7)*

5) *Onishi, N., et al., taken from the presentation made at the 31st Shikoku Dialysis Therapy Research Group, 1997 (Fig. 8, 9)*