



Nipro ELISIO™

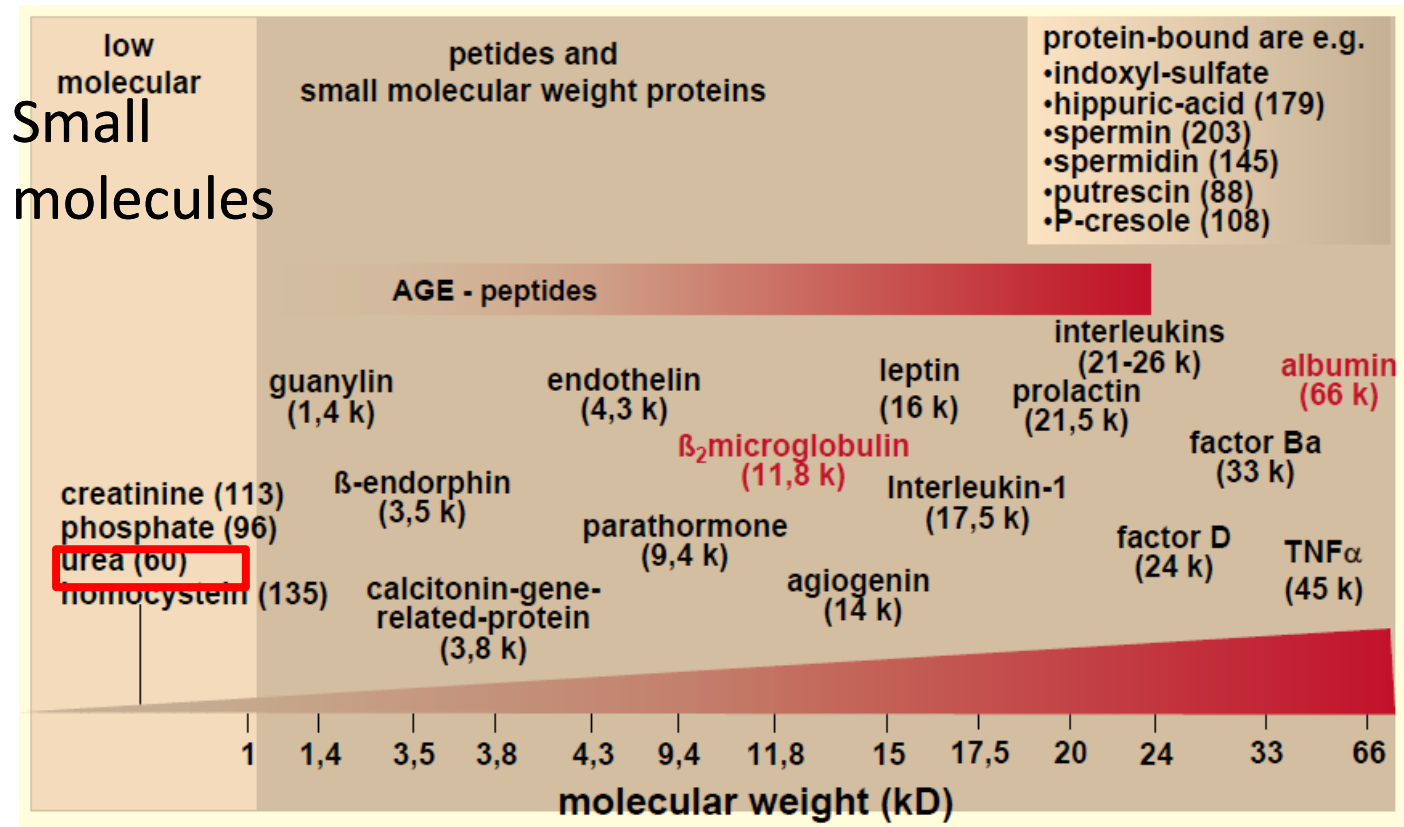
Benefits of Low Molecular Weight Protein Removal

Removal Target Molecules for LF/HF

- Low Flux(LF) Dialyzer
 - Small Molecules(URE/CRE/PHO)
 - MW up to 10,000 – Life sustaining

- High Flux(HF) Dialyzer
 - More Small Molecules, plus LMW Proteins such as β 2MG are linked to amyloidosis/CTS
 - MW < 66,000(ALB) – Clinical improvements

Uremic Toxins



- Myoglobin(17kD), is an important marker
- EPO inhibitor in range of 30,000-33,000

ELISIO Clinical Studies

Researchers	Hospital / University	ELISIO	Modality	Evaluation
Prof. Kresinski	CHU de Liege, BELGIUM	ELI-190H	Pre OL-HDF	Biocom.
Prof. Vanholder	UZ Gent, BELGIUM	ELI-170H+	HD / OL-HDF (pre / post-)	Removability on Uremic Toxins
Prof. Canaud	CHRU Montpellier, FRANCE	ELI-210H	HD / post OL-HDF	Biocom. Performance
Prof. Locatelli	Hosp. Lecco, ITALY	ELI-190H	HD / OL-HDF	Clinical Improvement
Dr. Puyol	Principe de Asturias Univ. Hosp., SPAIN	ELI-190H	HD	Biocom.
Dr. Davenport	Royal Free Hosp.	ELI-210H	HD	Coagulation
Dr. Krieter	Univ. Hosp. Wuerzburg GERMANY	ELI-190H	HD / pre OL-HDF	Performance Biocom.
Dr. Krieter	Univ. Hosp. Wuerzburg GERMANY	ELI-170M	HD	Performance Biocom.
Dr. Winkler	Rostock Germany	ELI-17H	HD	Performance etc.

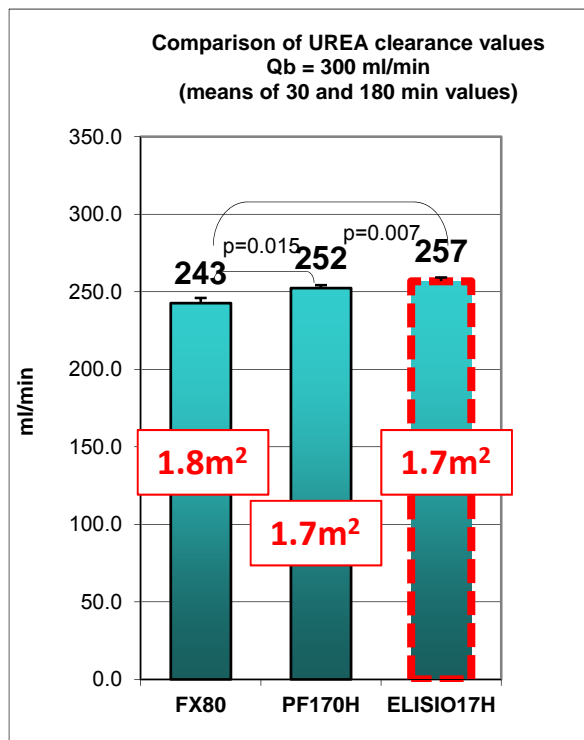


CLINICAL EVALUATION OF ELISIO-H IN GERMANY

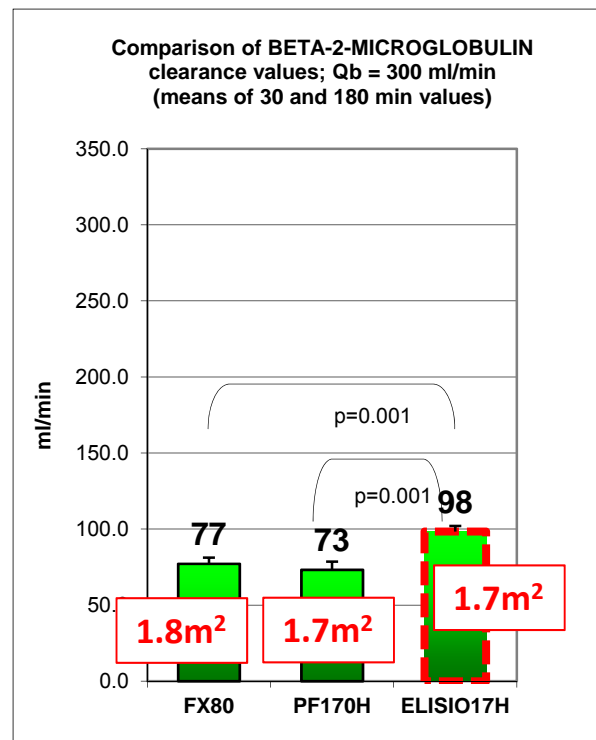
Clinical Evaluation of ELISIO-H in Germany

- 8 patients (M: 4 and F:4)
- Hemodialysis at Qb300 / Qd500, 1 week for each filter
- Dialyzers:
 - Gambro Polyflux-170H(1.7m²)
 - Nipro ELISIO-17H(1.7m²)
 - Fresenius FX80 (1.8m²)
- Parameters:
 - Small molecules CL: Ure / Cre / Pho
 - Middle molecules CL/RR: B2M / Myoglobin / ALB
 - Biocompatibility: WBC count / C5a / pmn-Elastase
 - Blood coagulation: PLT count / TAT / No of clotted fibers

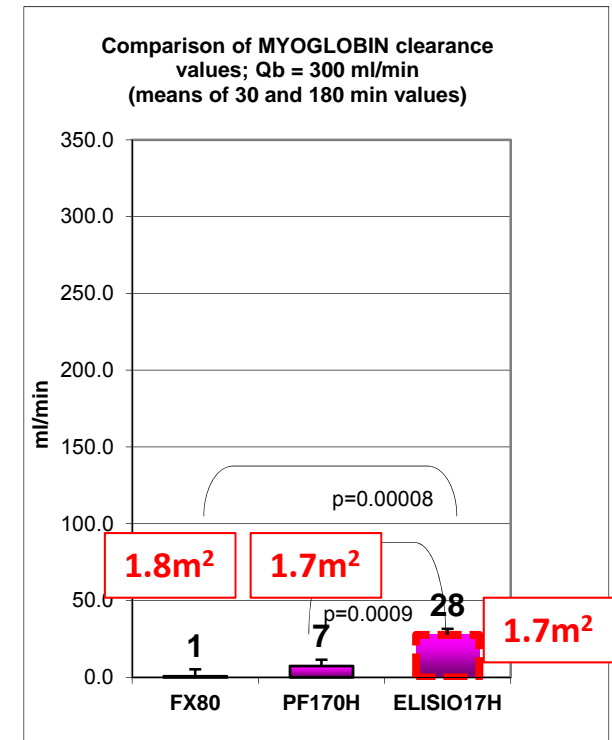
Clearances for Urea/B2M/Myoglobin



Urea (MW = 60)

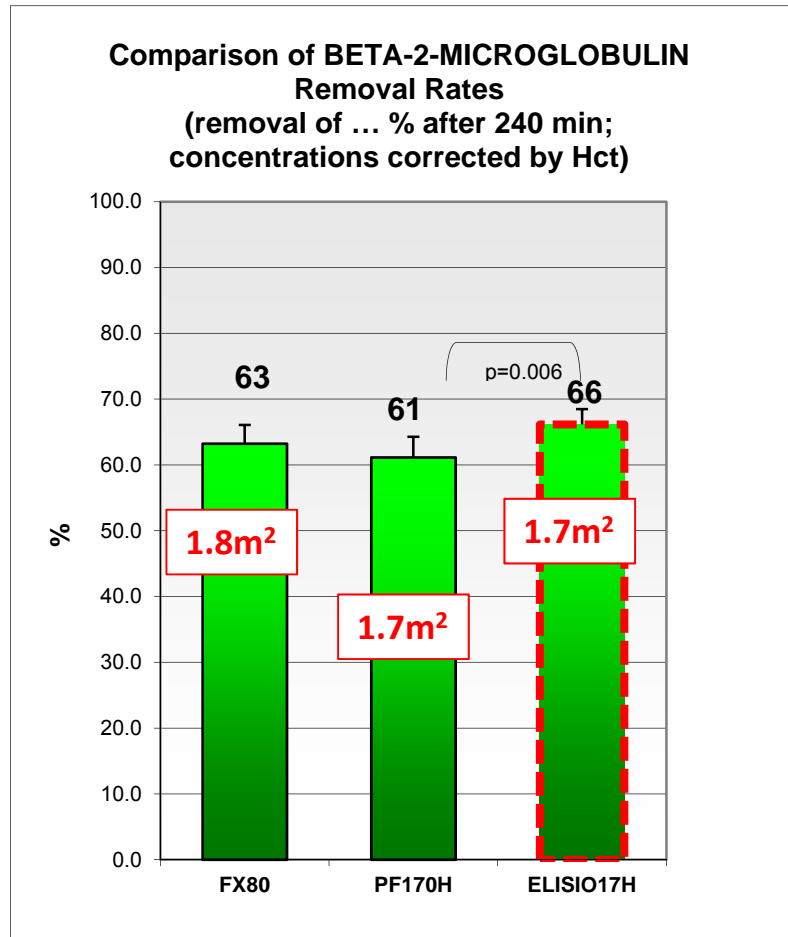


Beta-2-microglobulin (MW = 11,800)

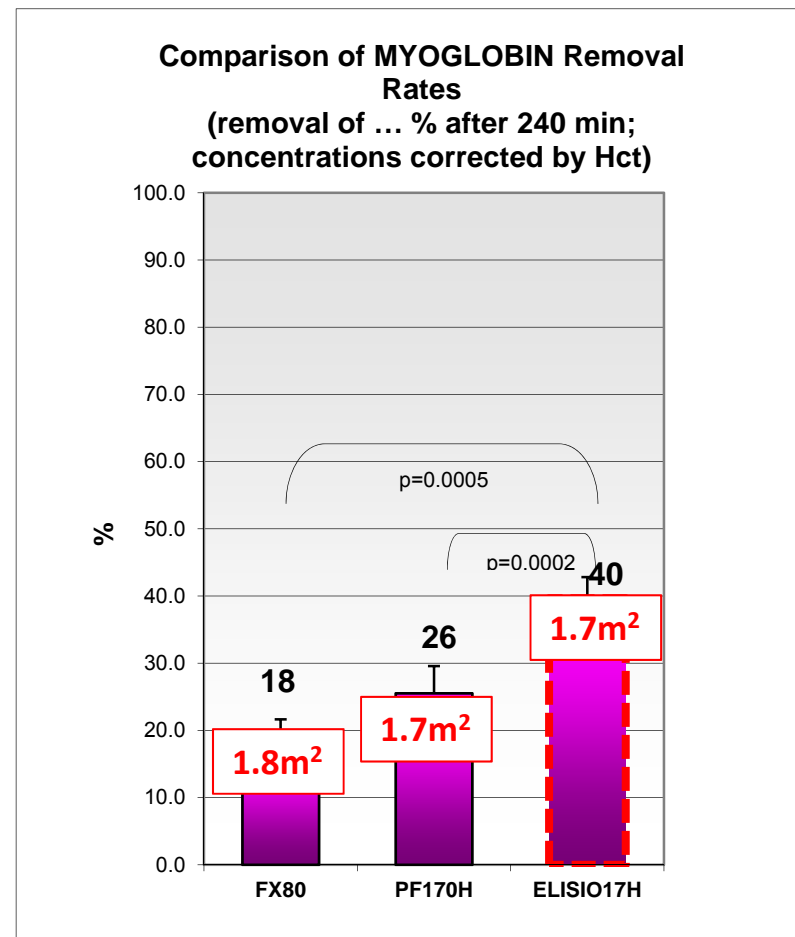


Myoglobin (MW = 17,000)

Removal rates for B2M and Myoglobin

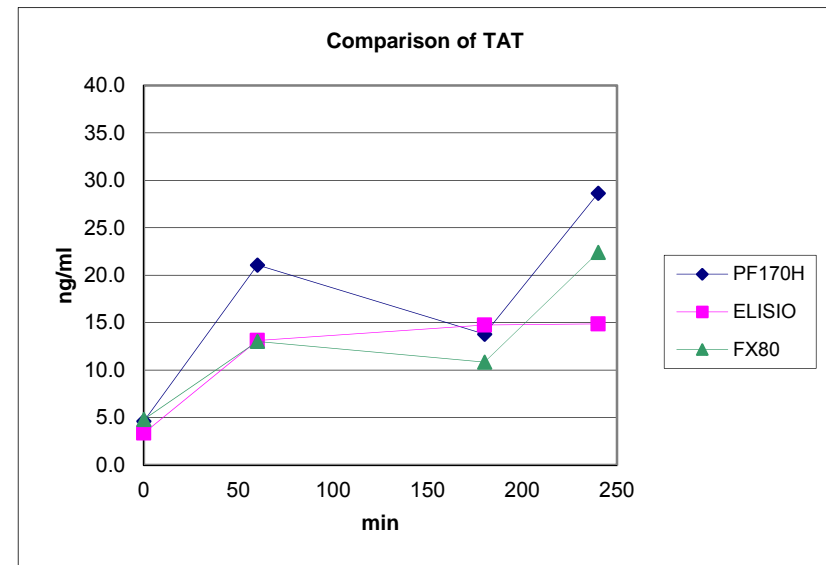
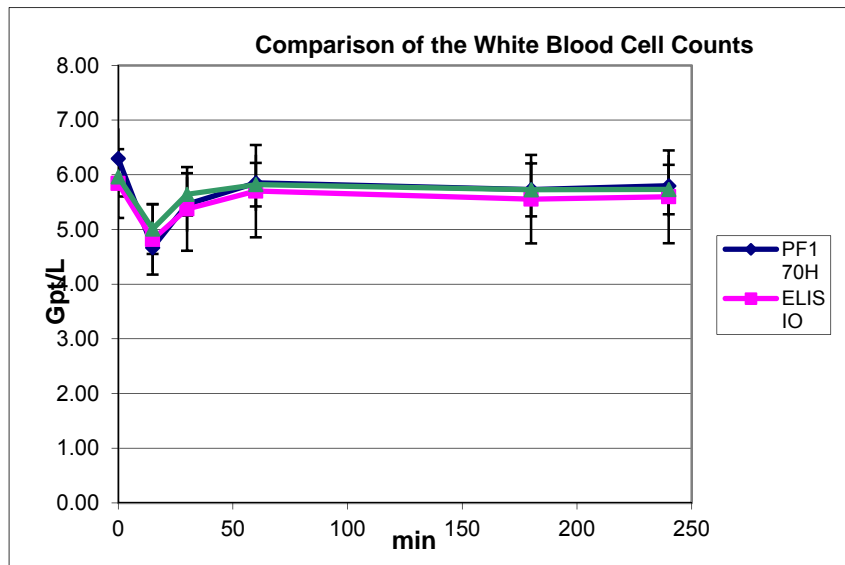


Beta-2-microglobulin (MW = 11,800)



Myoglobin (MW = 17,000)

Hemocompatibility Parameters



Condition : Qb300 / Qd500 HD

Evaluation on clotted filters

Visual Evaluation After Intensive Rinsing:

After the blood return, dialyzer fibers were rinsed by RO water in the RUF method, then fiber surface was observed.

grading:


red fibers	grade
0...10	1
11...20	2
21...50	3
51...100	4
>100	5

Patient	GP170H	ELISIO-17H	FX 80
	17/02/2010	24/02/2010	3/03/2010
	grade	grade	grade
HW	3	1	2
AS	2	1	1
MB	5	4	4
EM	3	2	1
RW	5	5	5
KB	4	3	3
BG	3	1	1
WW	5	1	5
mean:	3,8	2,3	2,8



CLINICAL EVALUATION OF ELISIO-H IN ITALY

Locatteli et al; "Prospective randomized pilot study on the effect of two synthetic high-flux dialyzers on dialysis patient anemia"; Int J Artif Organs 2012 - 35(5)346-351



Pilot Anemia Study (Hb Change)

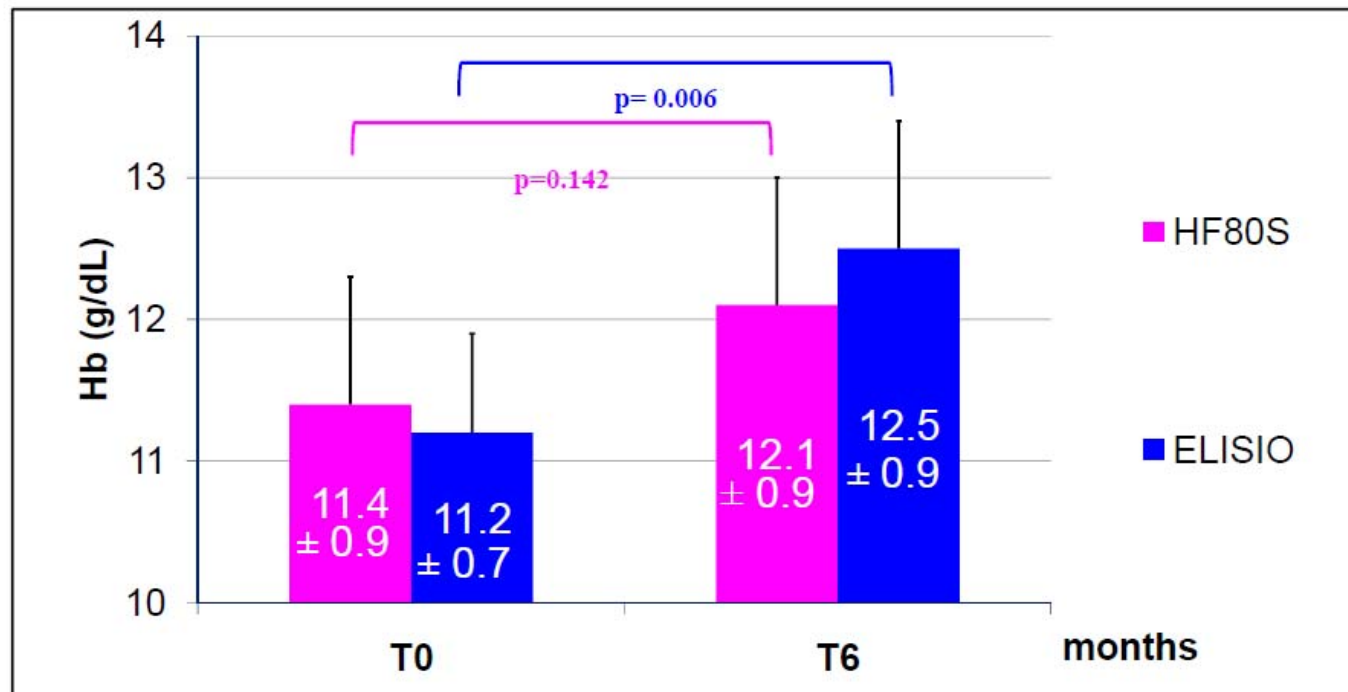


Figure 1:

Hemoglobin levels in g/dL at T0 and T6. Mean values \pm standard deviation are given. The increase is statistically significant in patients treated with the ELISIO-dialyzer ($p=0.006$)

Pilot Anemia Study (ESA Dosage)

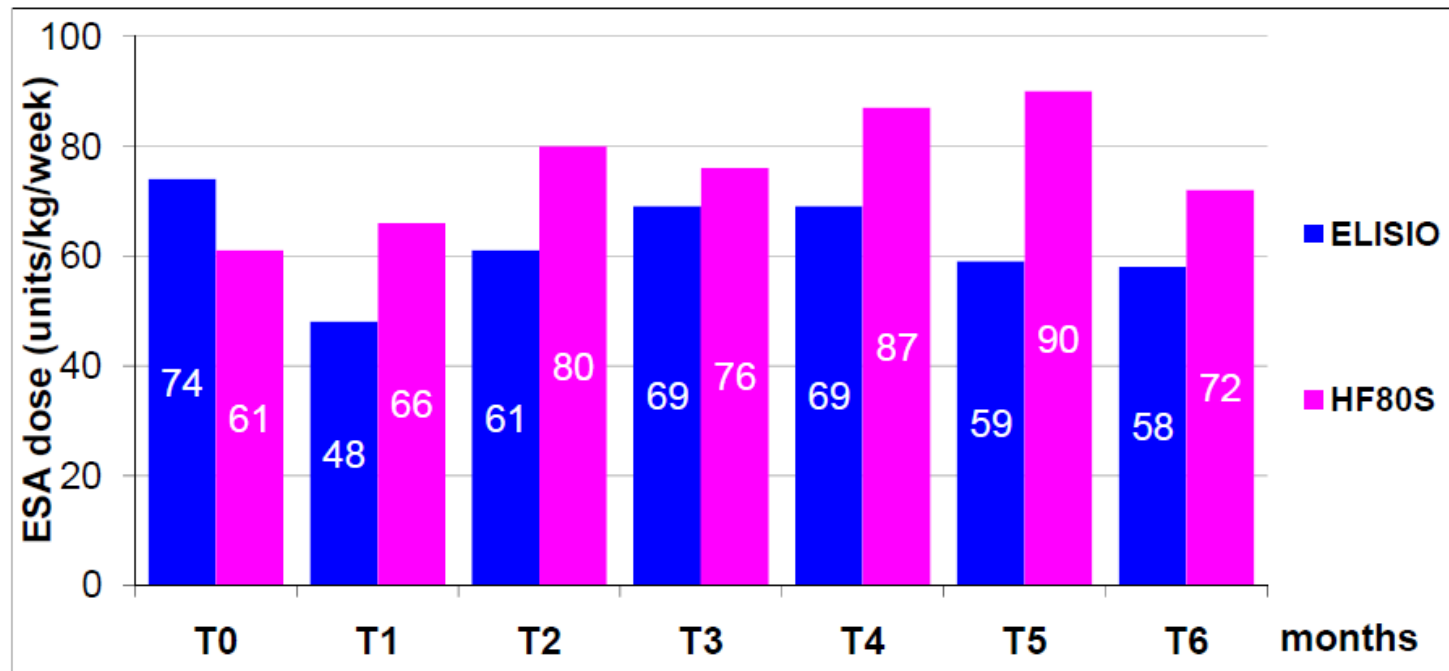


Figure 2:

ESA (Erythropoiesis Stimulating Agent) dose administered, in units/kg/week, at T0 until T6. The ESA/kg/week levels are not significantly different. However, ESA doses showed a tendency to increase for the HF group and tended to decrease in the ELISIO group.

Pilot Anemia Study (EPO Resistance Index)

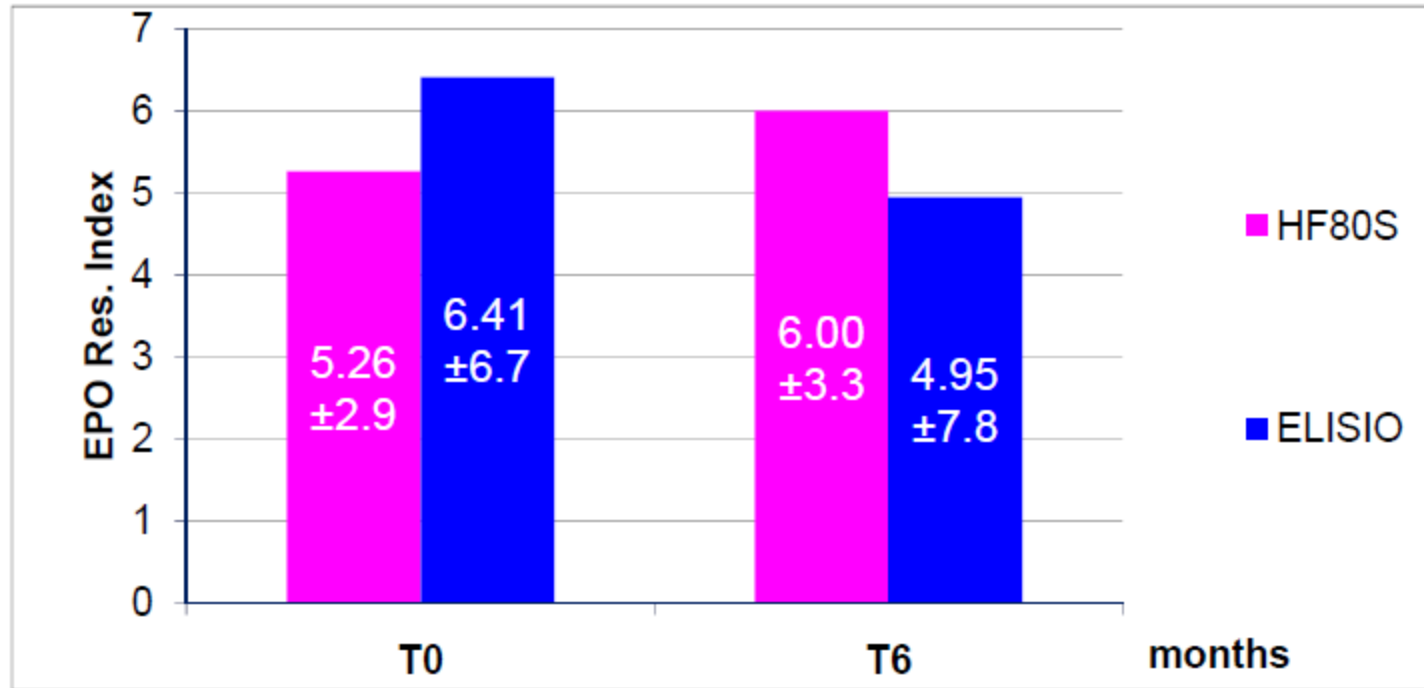


Figure 3:

EPO Resistance Index : For the ELISIO-group, there is a reduction of 22.7 % in EPO resistance index. For the HF80S, there is an increase of 14.0% in EPO resistance index. The differences between T0 and T6 are not statistically significant.

Summary

- Urea is an important uremic toxin, easy to measure and monitor
- There are many more uremic toxins to remove during hemodialysis that are related to clinical symptoms such as B2M and EPO inhibitors
- Based on a few clinical studies, ELISIO-H is better at removing other uremic toxins

