

Supportive xerostomia treatment with edible oral gel in dialysis patients



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Objectives:

A biopolymer based experimental oral hygiene gel contributed to optimal toothbrushing (Flad et al. 2016) and plaque control (Gaengler et al. 2016). Because of long bioavailability at the oropharyngeal mucosa and a low pH of 4.2, the reduction of xerostomia was expected. Therefore, it was the aim to assess (i) the reduction of dry-mouth symptomatology in dialysis patients, (ii) the improving of plaque control and (iii) the reduction of the number of gingivitis teeth.

Material and Methods:

After ethical approval (EK UWH 103/2019) 44 patients (18 female, 26 male; age 30 -85 y) with chronic renal failure (43 haemodialysis, 1 peritoneal dialysis) were randomized in 2 groups for 28 days. Inclusion criterion was sialometric flow rate <0.5 ml/min. Verum Group used edible oral gel containing chitosan and fluoride 2 x 2 minutes/day with a nursing multifunctional toothbrush, and the Control Group used the individual toothbrush and dentifrice for the same time. Instruction and clinical assessment took place at baseline, after 14 d and 28 d: Medical/dental status, Plaque Index (Silness/Loe), DMF/S, Gingivitis Teeth GPM/T (Gaengler), Denture Hygiene Index (Wefers), White Tongue (Grade 0-3) and OHIP-14 (German version). Most important was the dry-mouth assessment during dialysis and in-between usually 2x/week in 4 Grades (0 - never, 1 - sometimes, 2 - moderate, 3 - severe, 4-permanent). All data underwent statistical analysis for normal distribution (Kolmogorov-Smirnov-test), t-test for homogeneous variances, non-parametric WMW-U-test and Chi-Quadrat test using SPSS vers. 26. At baseline no significant differences between the two groups existed.

Results:

Compliance of subjects at dialysis periods and in-between was high. Xerostomia in Verum Group was reduced from baseline to 28 d End of Study from Grade 2.82 to 1.76 (Control Group stable at 2.14 - 2.24). However, xerostomia DURING dialysis decreased from 59.1% to 19.0% of subjects (Control Group stable at 50.0 - 52.4). The plaque Index was reduced from 1.44 to 0.99 (Control Group 1.35-1.16); and number of Gingivitis Teeth decreased from 7.56 to 4.76 (Control Group slight increase from 6.11 to 6.41). Even OHIP-14 improved from 6.62 to 4.75 in contrast to the Control Group (6.25 - 5.67). This was supported by the White Tongue Grades decrease from 1.73 to 1.14, in contrast to the Control Group increase from 1.73 to 1.95.

Conclusions:

The viscous oral care gel coating of the oropharyngeal mucosa with extended bioavailability contributed to highly significant (≤ 0.001) reduction of xerostomia, plaque accumulation and number of gingivitis teeth per subject. High compliance and the mechanism of action - MOA - in reducing dry-mouth complaints resulted in 20/1 (n = 21) claims to use the gel and the nursing multifunctional toothbrush in the future. Even in terminally ill patients, dentist's supervision and oropharyngeal gel improves Oral -Health related Quality of Life (OHIP).

References:

P. GAENGLER, C. BIRKE, B. JENNES and T. LANG, Planimetric plaque assessment of toothbrushing with agents of different abrasivity, Journal of Dental Research, 2016, Vol. 95, Spec. Issue, Abstract No. 0740

A-K. FLAD, T. LANG, K. WEICH and P. GAENGLER, In-vitro oral hygiene gel testing using organic plaque simulation. Journal of Dental Research, 2016, Vol. 95, Spec. Issue, Abstract No. 0741

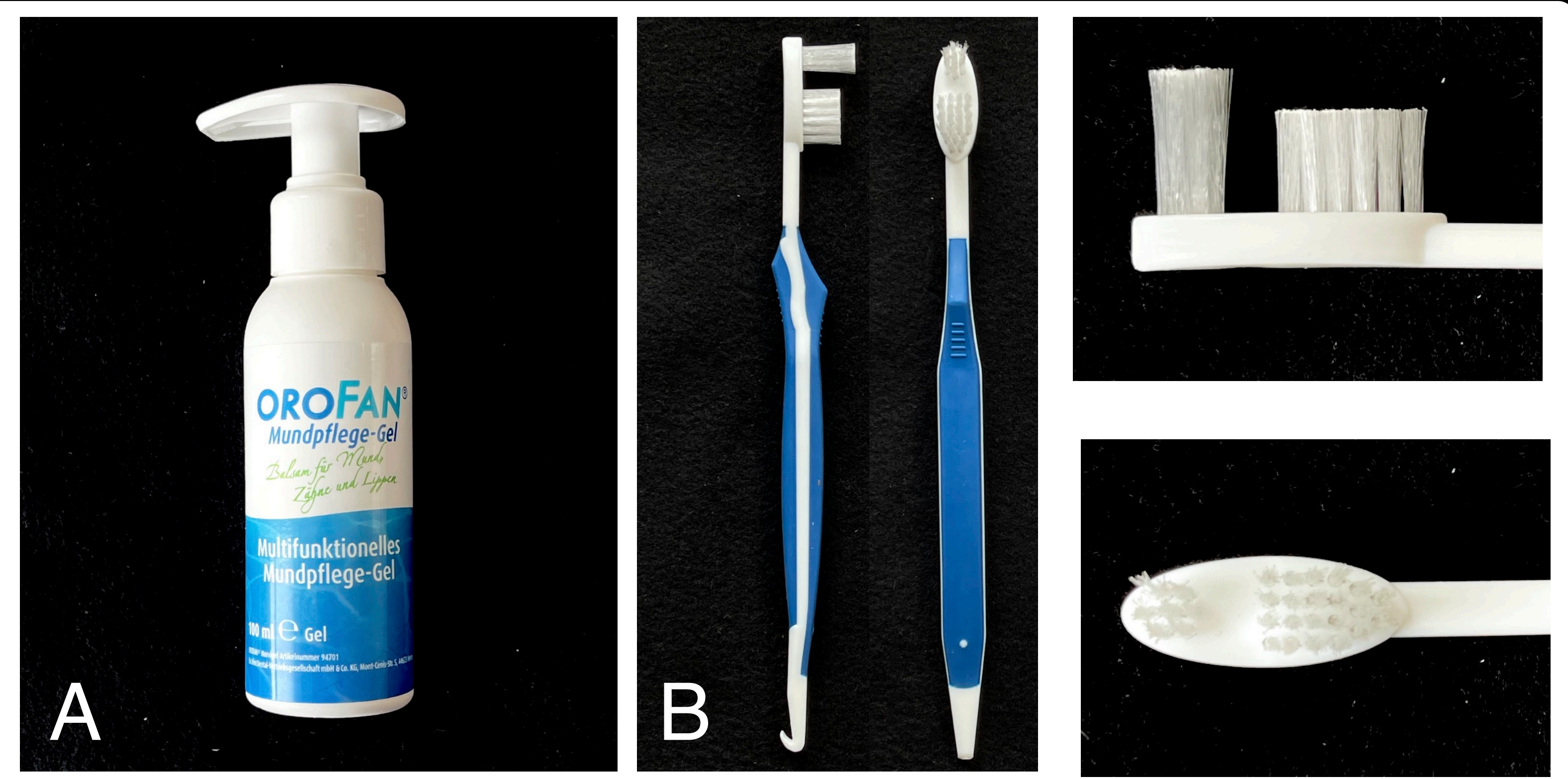


Fig. 1:
A - OROFAN - Oral Hygiene Gel, based on ChitoClear, xylitol, aloe vera, HEC, sodium fluoride (ORMED/Dr. Hinz Group, Herne, Germany)
B - OROFAN - Manual multifunctional toothbrush for nursing conditions (ORMED/ Dr. Hinz Group)

Fig. 2:
Clinical situation during dialysis at PHV. The study dentist, supervising the dialysis patient, explains the oral hygiene and assesses the plaque control and gingivitis reduction, contributing to improvement of Oral-Health related Quality of Life (OHIP-14)

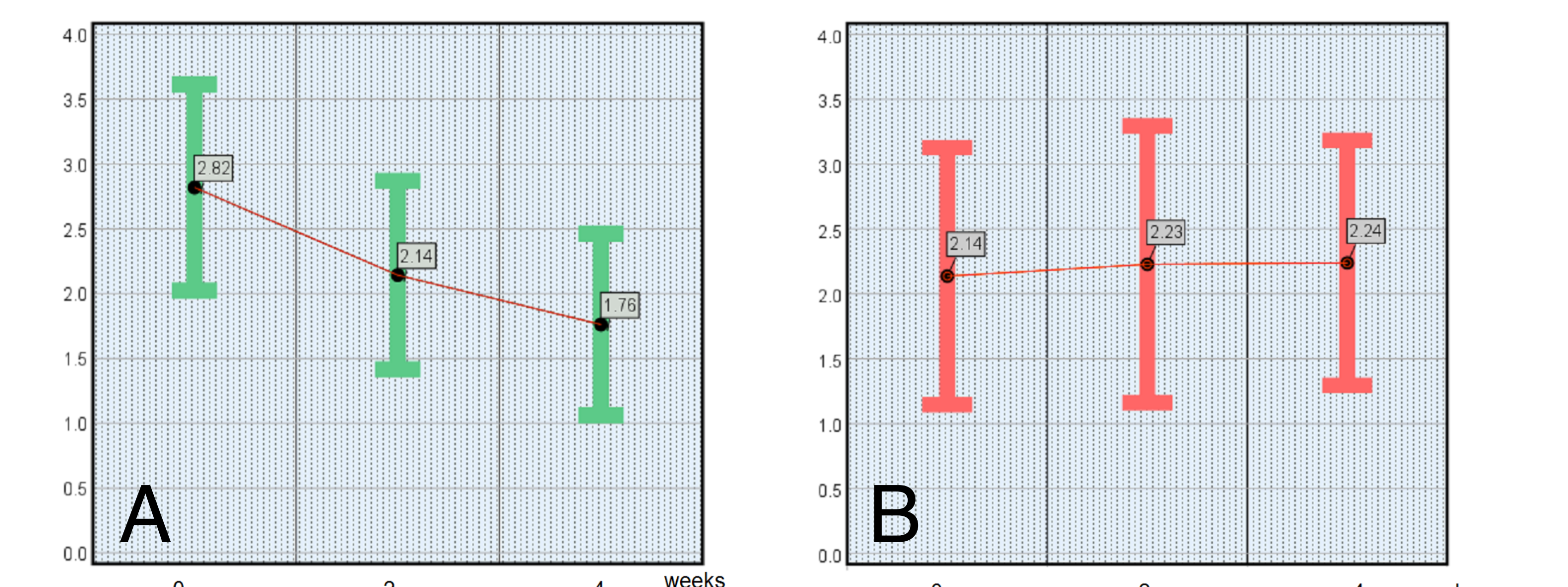
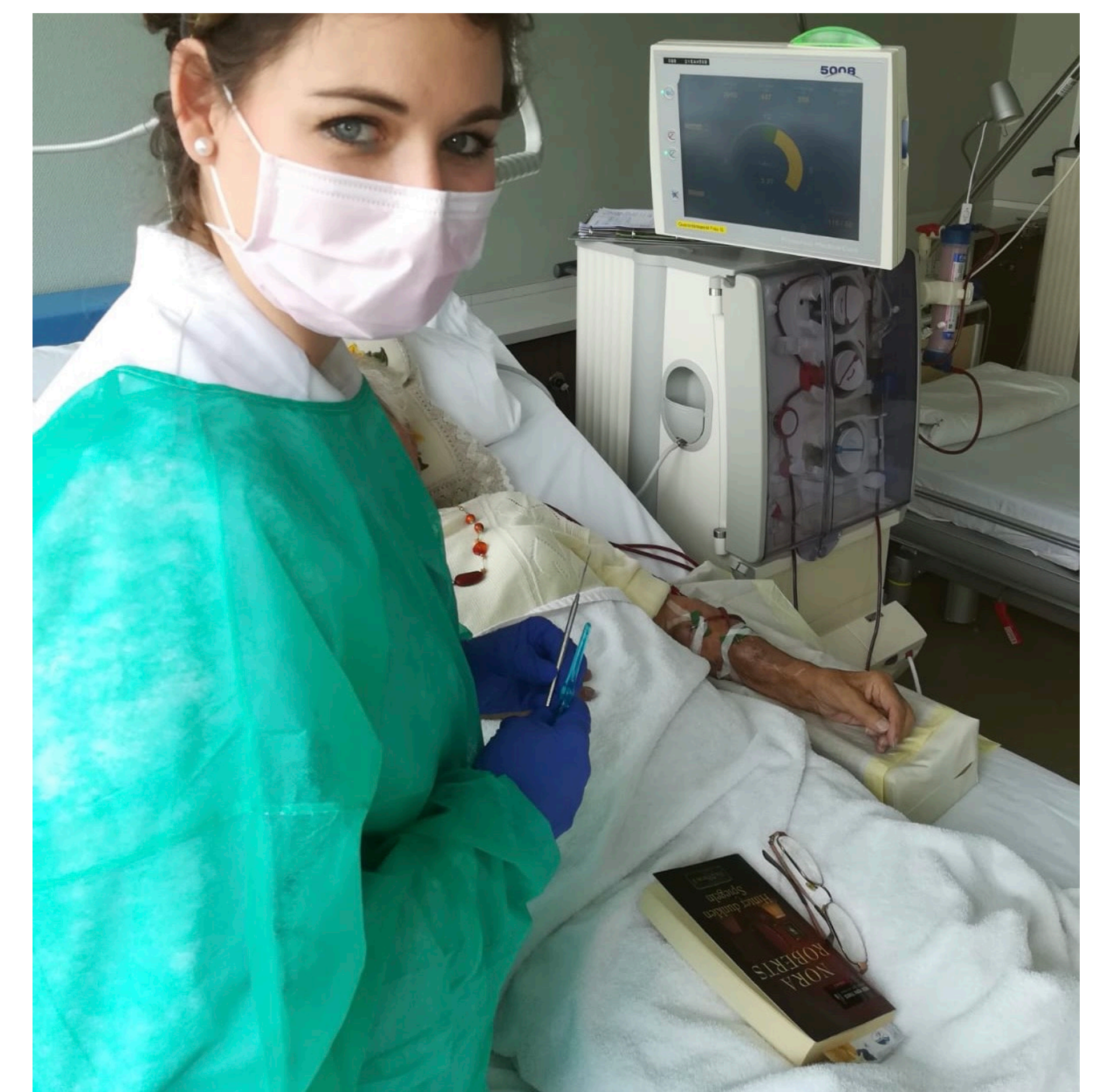


Fig. 3:
Frequency of dry mouth in verum group A, assessment in 4 Grades 0 - 4, compared to control group B with staple high values

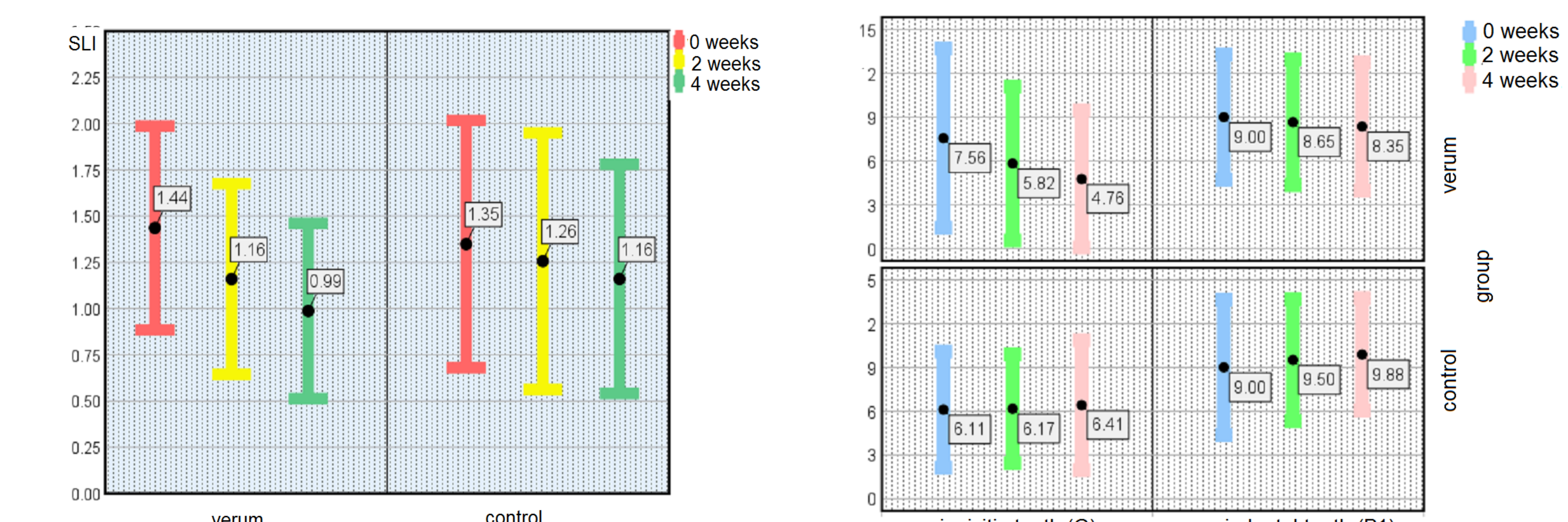


Fig. 4:
Plaque Index (SLI) over the test period of 2 and 4 weeks

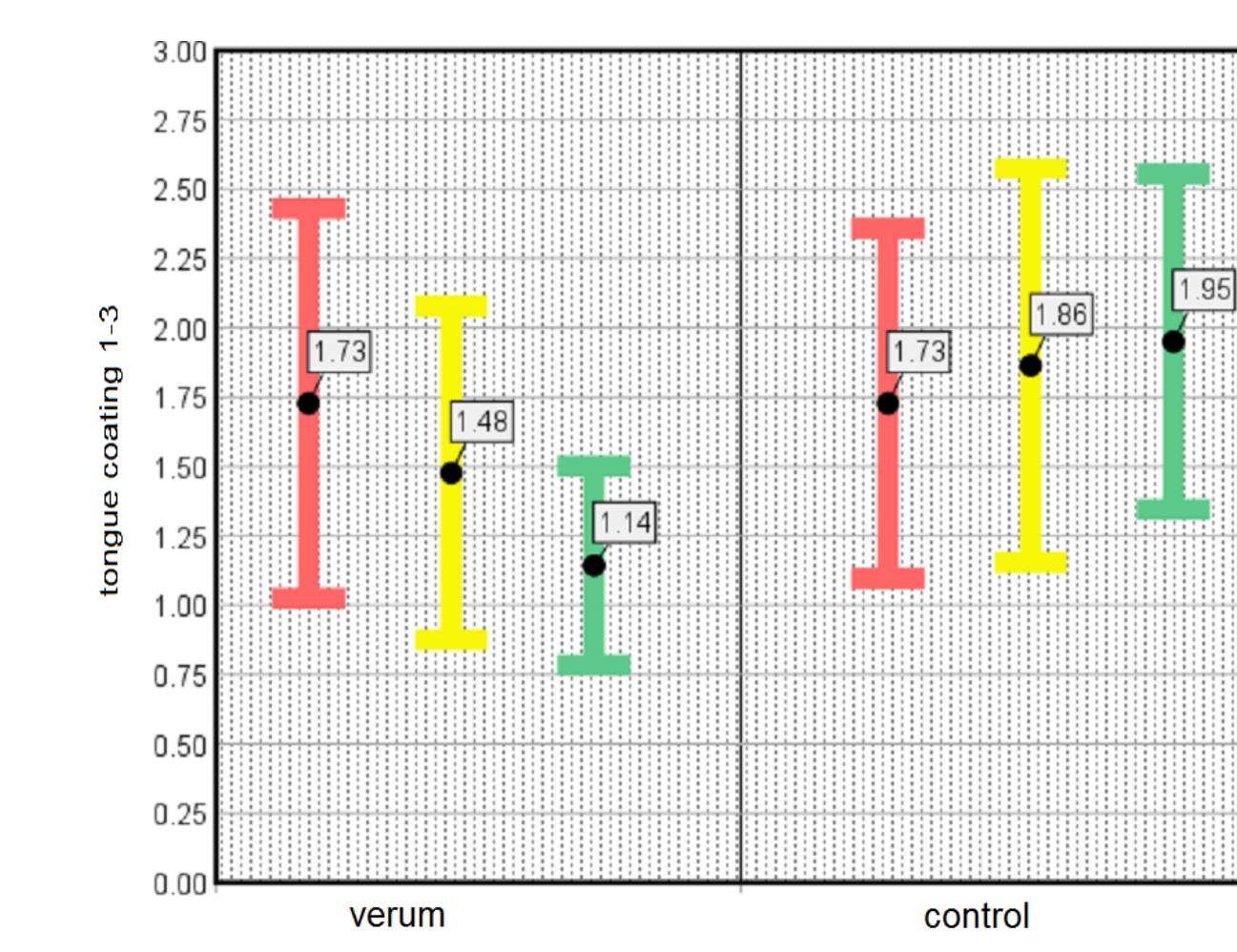


Fig. 5:
Number of Gingivitis teeth and Periodontitis teeth (shallow pockets) from BL to 4 weeks. Significant reduction of gingivitis in verum group

Fig. 6:
White Tongue Grades 0-3 with significant reduction after 4 weeks

Fig. 7:
OHIP-14 Scores with significant improvement of quality of life after 4 weeks in verum group

Tab. 1:
Stimulated salivary flow rate in verum group and control group at baseline examination, most subjects in both groups were classified with severe measured hyposalivation (physiological: > 1.0 ml/min, hyposalivation: 0.7-1 ml/min) pathological: < 0.7 ml/min)

Salivary flow rate (ml/Min.)	Verum Group	Control Group
< 0.7	18 (81.8 %)	19 (86.4 %)
0.7 - 1,0	4 (18.2 %)	3 (13.6 %)
> 1.0	0 (0.00 %)	0 (0.0 %)
Average rate	0.33 (0.00-0.98)	0.36 (0.08-1.00)

Tab. 2:
Study parameters at baseline and final examination in the verum group and in the control group

Parameter	Verum Group		p <	Control Group		P <
	Baseline (x +/- SD)	Final (x +/- SD)		Baseline (x +/- SD)	Final (x +/- SD)	
Dry mouth frequency	2.82 +/- 0.80	1.76 +/- 0.70	0.001	2.14 +/- 0.99	2.24 +/- 0.94	-
Dry mouth during dialysis (%)	59.10	19.00	0.01	50.00	52.40	-
SLI Plaque Index	1.44 +/- 0.55	0.99 +/- 0.47	0.001	1.35 +/- 0.67	1.16 +/- 0.62	-
White Tongue	1.73 +/- 0.70	1.14 +/- 0.36	0.01	1.73 +/- 0.63	1.95 +/- 0.60	0.1
Gingivitis teeth (n)	7.56 +/- 6.14	4.76 +/- 4.70	0.001	6.11 +/- 3.98	6.41 +/- 4.46	-
P1-shallow pockets (n)	9.00 +/- 4.30	8.35 +/- 4.39	0.05	9.00 +/- 4.63	9.88 +/- 3.85	-
DHI maxillary	33.89 +/- 22.45	61.14 +/- 29.48	0.05	28.33 +/- 18.37	34.50 +/- 26.09	-
DHI mandibulary	32.71 +/- 27.78	51.14 +/- 18.14	0.05	36.67 +/- 40.33	44.00 +/- 40.37	-
OHIP-14	6.62 +/- 5.74	4.75 +/- 5.02	0.01	6.25 +/- 6.36	5.67 +/- 5.7	-

Tab. 3 A-B:
Statistical differences after 2 weeks (A) and after 4 weeks (B).

Parameter	Test size of the test	df	p	Applied test
Frequency of dry mouth	3.873**	1	0.000	Wilcoxon-Test (n=21)
Dry mouth with dialysis	25.2%	1	0.250	McNemar-Test (n=21)
DMF/S	Variance of change close to zero			
SLI	7.738***	16	0.000	t-Test (n=17)
G (from GPM/T)	3.269***	1	0.001	Wilcoxon-Test (n=17)
P1 (from GPM/T)	-1.732**	1	0.083	Wilcoxon-Test (n=17)
DHI (maxillary)	-2.375*	1	0.018	Wilcoxon-Test (n=8)
DHI (mandibulary)	-2.207*	1	0.027	Wilcoxon-Test (n=7)
OHIP-14	No data at the interim review			
Tongue coating	-1.890**	1	0.059	Wilcoxon-Test (n=21)