Plaque Control with Lamellar Full-Mouth Device - Randomized Clinical Crossover Study

IADR 2022
Presentation/ Poster #: 1266

P. GAENGLER*[1)], T. LANG[1)], K. Grotzky[1)], M. KEINER[2)] and K. W. WEICH†

1) **ORMED** - Institute for Oral Medicine at the University of Witten/Herdecke, Germany
eMail: info@ormed.net, web: www.ormed.net
2) **BLBR** GmbH, Gruenwald, Germany, www.uniqe.com

Objectives:

Lamellar full-mouth device (Uniqe, BLBR, Gruenwald, Germany) with brushing-vibrating mechanism of action (MOA) combined with dentifrice foam (Uniqe Flow) was effective in clinically validated robot testing (Gaengler et al., 2021; Lang et al., 2021)

The objective of this explorative investigator-blinded cross-over RCT was to assess clinical efficacy versus sonic toothbrushing (Philips Sonicare, Drachten, Netherlands). (German Clinical Trials Register DRKS00024136)

Material and Methods:

21 participants (18-65 years of age, 20 teeth min and 32 teeth max, 2 urban dental-offices) were randomly assigned to Arm1 (Uniqe + UniqeFlow 1450ppm fluoride, 60s with chewing and manual horizontal movements) or Arm2 (Philips + Sensodyne Extra Frisch 1450ppm fluoride, 120s gliding motions from tooth group to tooth group).

Following instructed first application 3 days after professional tooth cleaning, participants continued brushing twice daily at home for 3 weeks.

After one week wash-out and professional tooth cleaning (Day 1) participants changed the product.

On day 4, day 11, day 18, day 25 stained plaque was photographed before and after supervised brushing, planimetrical plaque index (PPI, 18 coronal fields) and occlusal planimetrical plaque index (oPPI, 2/4 fields per posterior tooth) was assessed with codes 0 – no plaque, 1 - <50% plaque covered field surface, 2 - >50% plaque covered surface at all single planimetrical fields at all teeth.

Primary outcome was plaque control, calculated as delta-value for each planimetrical field before and after brushing. Seventy plaque variables (3 plaque codes x 18 coronal planimetrical fields + 12 occlusal fields at molars and 4 occlusal fields at premolars) were statistically analysed first by Kolmogorov-Smirnov-test and Shapiro-Wilk-test for normal distribution, followed by the dependent two-sample-t-test.

Results:

21 participants completed the study. Both brushing methods were well accepted and tolerated.

Overall plaque control demonstrated matching results for both devices throughout the study (51-100%, code 2).

Hidden interdental risk areas (lingual and palatinal) were equally well cleaned (delta-Code around 0.5=50%) as well as all occlusal fields (oPPI 0.42 versus 0.43).

Easily accessible vestibular areas were better controlled by Philips (PPI 0.71 versus 0.35).

Conclusions:

Lamellar full-mouth device Uniqe with brushing-vibrating MOA delivers optimal plaque control combined with constant fluoride bioavailability.

Hidden risk areas and occlusal surfaces are equally well cleaned as with sonic device.

Further clinical investigation of unsupervised use should elucidate clinical efficacy and advantages for defined user groups.

Sponsored by BLBR, Gruenwald, Germany.

The authors PG, TL and KG declared no potential conflicts of interest with respect to the research, authorship and publication of this interactive talk.

MK is CEO and Head of product development. He is also a minor shareholder of BLBR GmbH.

Fig. 1:
A - **Uniqe Serial Product shown with S-Mouthpiece**
B - **Uniqe Flow dentifrice**
C - **Philips Sonicare Diamond Clean with Sensitive Head**
D - **Sensodyne Sensitiv Extra Frisch**

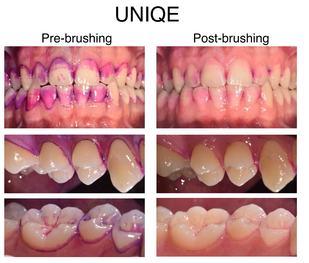

Fig. 2:
Subject Nr. 7 / D 25
Stained plaque

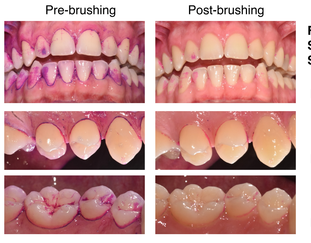

Fig. 3:
Subject Nr. 7 / D 25
Stained plaque

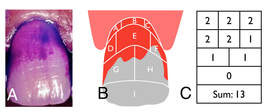

Fig. 4: Planimetrical fields at human teeth (A), clinical brushing outcome (B), Planimetrical Plaque Index PPI Scores (Lang et al. 2011) (C)

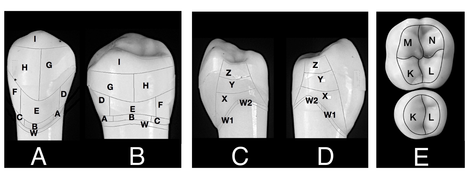

Fig. 5:
Planimetrical fields at tooth crowns and roots of smooth surfaces (A,B) and mesially (C) and distally (D) in-between the teeth for plaque assessment in percentages per field, per risk area or per tooth site with automated plaque planimetry APP according to the Planimetrical Plaque Index PPI; oPPI at molars, occlusal planimetrical fields K and L mesially and M and N distally (E); below: oPPI at premolars, planimetrical fields K buccally and L lingually (Gaengler et al. 2021) (E).

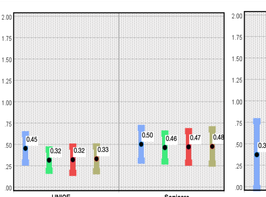

Fig. 6: Error bars for Total plaque removal (PPI) (fields A – I, maxilla + mandible) palatinal/lingual on days 4 - 25: means and standard deviations for UNIQE and Sonicare

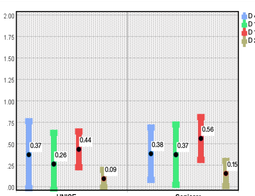

Fig. 7: Error bars for plaque removal at lingual risk areas ABC next to gum line (PPI) (mandibular teeth 33, 34, 35, 43, 44, 45) on days 4 - 25: means and standard deviations for UNIQE and Sonicare

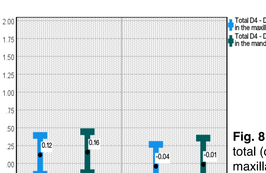

Fig. 8: Error bars for plaque removal (PPI) total (difference day 4 – day 25) in the maxilla and in the mandible: means and standard deviations of Delta PPI values for UNIQE and Sonicare

Parameter	Statistic		
	t	df	p
ABC palatinal max. d 4	1.043	20	0.310
DF palatinal max. d 4	-0.480	16	0.641
ABC lingual mand. d 4	-0.201	19	0.842
DF lingual mand. d 4	-2.035	19	0.056
ABC palatinal max. d 11	-1.620	18	0.123
DF palatinal max. d 11	-1.194	19	0.247
ABC lingual mand. d 11	-1.434	19	0.168
DF lingual mand. d 11	0.687	17	0.501
ABC palatinal max. d 18	-1.510	19	0.147
DF palatinal max. d 18	-0.699	16	0.494
ABC lingual mand. d 18	-2.612*	19	0.017
DF lingual mand. d 18	-1.502	14	0.155
ABC palatinal max. d 25	-2.229*	19	0.038
DF palatinal max. d 25	-1.667	20	0.111
ABC lingual mand. d 25	-2.235*	19	0.038
DF lingual mand. d 25	-1.610	19	0.124

Tab. 1: Dependent t-Test of cleaning efficacy parameters (PPI) of teeth numbers 13, 14, 15, 23, 24, 25 (maxilla) and 33, 34, 35, 43, 44, 45 (mandible) between UNIQE and Sonicare (Days (d) 4, 11, 18, 25). Most risk areas next to the gum line ABC and interdentally DF do not exhibit statistical differences, only three risk areas next to the gum line ABC lingually in upper and lower jaw and palatinally in upper jaw show statistical better plaque removal ($p<0.05$).

Statistical rationale:
max. = maxilla
mand. = mandible
t = test statistic of the dependent t-test
df = degrees of freedom
p = significance value
* significant ($p \leq 0.05$)
** very significant ($p \leq 0.01$)
*** highly significant ($p <= 0.001$)