



INDIANA UNIVERSITY

SCHOOL OF DENTISTRY
Oral Health Research Institute
IUPUI

FINAL REPORT # 18-PCR-99

TITLE

DETERMINATION OF THE CLEANING ABILITY OF TOOTH POWDERS TO REMOVE STAINED PELLICLE

STUDY SPONSOR

LoveSmiles Pty Ltd
5 harbour rise hope island
4212 Gold Coast - Hope Island
Queensland – Australia

Attention: Urissa Chinia

CONDUCTING AGENCY

Indiana University School of Dentistry
Oral Health Research Institute
415 Lansing Street
Indianapolis, Indiana 46202-2876
Website: <http://www.ohrilab.dentistry.iu.edu/>

Study Director: Anderson T. Hara, DDS, MS, PhD
(317) 278-0577

Research Technician: Glynis Odle

PURPOSE

The purpose of this study was to determine the cleaning ability of one tooth powder to remove stained pellicle.

BACKGROUND

This laboratory test was developed in order to assess the ability of dentifrices to remove stained pellicle, i.e., to determine the cleaning ability of complete dentifrice formulations. Previous studies (J. Dent. Res., 61:1236, 1982) have indicated that the results of this test with dentifrice slurries compare favorably with those obtained in controlled clinical trials. Thus, the results of this test using dentifrice slurries may be considered to predict clinical findings with a reasonable degree of confidence.

TEST PRODUCTS

The product was provided and coded by the Sponsor. The Sponsor was responsible for the identity, strength, purity, and composition or other characteristics of the test product. The products tested in this study was assigned to groups by the OHRI technician and labeled as follows:

Group	Product
A	ADA Reference Material
B	LOVESMILES NATURAL ACTIVATED COCONUT SHELL CHARCOAL

MATERIALS AND METHODS

Specimen Preparation

Bovine, permanent, central incisors were cut to obtain labial enamel specimens approximately 10 X 10 mm. The enamel specimens were embedded in an autopolymerizing methacrylate resin so that only the enamel surfaces were exposed. The enamel surfaces were then smoothed and polished on a lapidary wheel and lightly etched to expedite stain accumulation and adherence. They were placed on a rotating rod (~37°C incubator), which alternately exposed them to air and to a solution consisting of PGY broth, tea, coffee, mucin, FeCl₃, and *Micrococcus luteus*.¹

The staining broth was changed and specimens rinsed daily until a uniform stain had accumulated. After approximately seven days, a darkly stained pellicle film was apparent on the enamel surfaces. Specimens were rinsed, allowed to air dry, and refrigerated until used. All products were tested using specimens prepared at the same time.

Scoring and Set-Up

The amount of *in vitro* stain was graded photometrically using only the L value of the L*a*b* scale using a spectrophotometer (Minolta CM2600d). The area of the specimens scored was a 1/4-inch diameter circle in the center of the 10 X 10 mm enamel. Specimens with scores between 30 and 42 (30 being more darkly stained) were used. On the basis of these scores, the specimens were divided into groups of 16 specimens each, with each group having approximately the same average baseline score.

Procedure

The specimens were mounted on a mechanical V-8 cross-brushing machine equipped with soft nylon-filament (Oral-B 40) toothbrushes. Tension on the enamel surface will be adjusted to 150 g. The tooth powder was tested as slurry prepared by mixing 6 g of product with 60 ml deionized water². The reference material was the ADA Reference Material (10g of Ca₂P₂O₇/50ml 0.5% CMC). The specimens were brushed for 800 strokes (4 1/2 minutes).

To minimize mechanical variables, two specimens per group was brushed on each of the eight brushing heads. Different test products were used on each run, with one tube of slurry made up for each product. Fresh slurry was made after being used to brush four specimens. Following brushing, specimens were rinsed, blotted dry, and scored again for stain, as previously described.

Calculations

The mean decrement between the pre- and post-brushing stain scores was determined for the ADA Reference Material group, and assigned a pellicle cleaning ratio (PCR) value of 100. A constant value was calculated by dividing the mean decrement of the ADA Reference Material into 100. The individual PCR value for each specimen was calculated by multiplying its individual decrement by the calculated constant. The mean, standard deviation and SEM (standard error of the mean) for each test group (N=16) were then calculated using the individual PCR values. The larger the PCR value, the greater the amount of stained pellicle removed from the enamel surface in this test.

DATA MANAGEMENT AND ANALYSIS

Data was analyzed using a t-test model (Sigma Plot Software v.12.0). All analyses were done with the significance level set at 0.05.

¹ This solution had its original formulation (J. Dent. Res. 61:1236, 1982) modified by the addition of FeCl₃ and substitution of the PGY broth. FeCl₃ was added to compensate for the lower concentration of iron in the new type of gastric mucin that started being used, late in 1997. The supplier of *Micrococcus luteus* was changed in 2012, which led to the substitution of PGY broth for trypticase soy broth for optimal growth.

² Product mixing instructions reference: Pascaretti-Grizon F, Mabilieu G, Chappard D. Abrasion of 6 dentifrices measured by vertical scanning interference microscopy. J Appl Oral Sci. 2013 Sep-Oct;21(5):475-81.

TIMETABLE

This study was conducted on July 17-18, 2018.

RECORDS MAINTAINED

OHRI will be responsible for the storage and destruction of the test products and specimens in accordance with standard operating procedures. The study raw data and documents will be maintained for a minimum of 4 months after Final Report approval. Electronic files of all study data and documents will be maintained for a minimum of 10 years.

RESULTS AND CONCLUSIONS

The results are summarized in the following table, where PCR means (\pm SEM) are listed in descending order (higher mean PCR values represent higher efficacy on stained pellicle removal). The pre- and post-brushing scores and calculations are provided in the attached tables.

Based on the statistical analysis and considering the ranking order provided in the table:

The ADA Reference Material was more effective than LOVESMILES NATURAL ACTIVATED COCONUT SHELL CHARCOAL in stained pellicle removal.

SUMMARY OF PELLICLE CLEANING RATIO DATA ON TOOTH POWDER


Product	Sample Size (N=16)*	Pellicle Cleaning Ratio**
ADA Reference Material	15	100.00 \pm 2.39
LOVESMILES NATURAL ACTIVATED COCONUT SHELL CHARCOAL	16	80.55 \pm 2.34

* Missing values due to outlier data
** Mean \pm SEM
Groups differ significantly (P<0.05)

FINAL REPORT APPROVALS

The following date and signature indicates that the Study Director has reviewed and approved the foregoing final report.

STUDY DIRECTOR



Anderson T. Hara, DDS, MS, PhD
Director, Laboratory Contract Testing Program

7-20-18

Date


The following date and signature indicates that the Quality Assurance Manager has reviewed and approved the foregoing final report. The Quality Assurance Manager report was submitted to the Study Director as follows:

Phase
Data Audit
Draft Report Review
Report to Study Director and Management

Date
7/20/2018
7/20/2018
7/20/2018

This Final Report accurately reflects the raw data.

QUALITY ASSURANCE



Robin Johnson, RHIA
Quality Assurance Manager

7/20/2018

Date

SPECIMEN	STUDY GROUP PRODUCT			18-PCR-99 A <u>ADA Reference</u>
	<u>Pre</u>	<u>L Value</u> <u>Post</u>	<u>Delta</u>	<u>Pellicle</u> <u>Cleaning</u> <u>Ratio</u>
29	*	*	*	*
10	30.7	61.3	30.5	116.5
5	31.0	58.6	27.6	105.4
33	31.4	57.6	26.2	99.8
13	31.5	58.2	26.7	102.0
28	31.8	52.2	20.4	77.8
63	31.9	57.4	25.5	97.4
89	32.4	58.0	25.6	97.8
52	32.4	59.5	27.1	103.3
58	32.9	61.4	28.6	108.9
74	32.9	60.6	27.7	105.6
25	34.0	62.4	28.5	108.6
67	34.2	59.0	24.8	94.7
66	35.3	58.6	23.3	88.9
73	35.3	59.8	24.5	93.5
81	38.0	64.2	26.2	99.8
MEAN	33.05	59.26	26.22	100.00
STD. DEV.	2.00	2.74	2.42	9.24
STD. ERR.	0.52	0.71	0.63	2.39

#29 was rejected due to outlier data

SPECIMEN	STUDY GROUP PRODUCT		18-PCR-99 D LOVESMILES NATURAL ACTIVATED COCONUT SHELL CHARCOAL	
	<u>Pre</u>	<u>L Value</u> <u>Post</u>	<u>Delta</u>	<u>Pellicle</u> <u>Cleaning</u> <u>Ratio</u>
6	30.2	54.6	24.4	93.1
23	30.5	51.6	21.1	80.3
86	31.1	56.6	25.5	97.3
15	31.3	52.7	21.4	81.6
90	31.6	54.2	22.7	86.4
22	31.7	53.8	22.0	84.1
76	32.0	53.9	22.0	83.8
31	32.2	54.7	22.5	85.8
83	32.5	50.1	17.6	67.1
36	32.8	52.5	19.7	75.1
69	33.2	55.3	22.1	84.3
18	33.8	56.7	22.9	87.3
45	34.3	54.1	19.8	75.7
77	35.0	55.0	20.0	76.5
96	35.7	53.4	17.8	67.8
82	36.7	53.1	16.4	62.6
MEAN	32.79	53.91	21.12	80.55
STD. DEV.	1.86	1.70	2.46	9.38
STD. ERR.	0.46	0.43	0.61	2.34