



INDIANA UNIVERSITY

SCHOOL OF DENTISTRY
Oral Health Research Institute
IUPUI

FINAL REPORT # 18-RDA-93

TITLE

DETERMINATION OF THE RELATIVE DENTIN ABRASION LEVEL OF POWDER

STUDY SPONSOR

LoveSmiles Pty Ltd
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Attention: Urissa Chinia

CONDUCTING AGENCY

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Research Technicians: Ro Ding

PURPOSE

The purpose of this study was to determine the relative abrasion level of one powder.

BACKGROUND

The procedure used in this study was the Hefferren abrasivity test recommended by the ADA and ISO 11609 for determination of dentifrice abrasiveness in dentin. The abrasivity limit specified by the ISO 11609 at 2.5x that of the reference material (Ca₂P₂O₇) may be considered in the interpretation of the results of this test. Therefore, since the current protocol has assigned an arbitrary value of 100 to the reference material, the RDA abrasivity limit is 250.

TEST PRODUCTS

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

Group	Product
D	LOVESMILES NATURAL ACTIVATED COCONUT SHELL CHARCOAL

MATERIALS AND METHODS

Specimen Preparation

Eight (8) human dentin specimens were subjected to neutron bombardments resulting in the formation of radioactive phosphorus (³²P) within the specimens under the controlled conditions outlined by the ADA. The specimens were mounted in methyl methacrylate so they fit in a V-8 cross-brushing machine. The specimens were brushed for a 1500 stroke, precondition run using slurry consisting of 10g ADA reference material in 50 ml of a 0.5% CMC glycerin solution. The brushes used were those specified by the ADA with a brush tension of 150g.

Procedure

Following the precondition run, the test was performed using the above parameters (150g and 1500 strokes) in a “sandwich design.” Before and after brushing with the test product (6 g product/60 ml deionized water¹) each tooth set was brushed with the ADA Reference Material (10g of Ca₂P₂O₇/50ml 0.5% CMC). The procedure was repeated additional times so that the product was assayed on each tooth set. The treatment design was the modified Latin Square design so that no treatment followed another treatment consistently.

Calculations

One ml samples was taken, each weighed (~1g), and added to 5 ml of “Ultima Gold’ scintillation cocktail. The samples were mixed well and immediately put on a liquid scintillation counter for radiation detection. Following counting, the net counts per minute (CPM) values were divided by the weight of the sample to calculate a net CPM/gram of slurry. The net CPM/g of the pre and post ADA Reference Material for each of the test slurries was calculated and averaged to use in the calculation of RDA (relative dentin abrasion) for the test material. The ADA Reference Material was assigned a value of 100 and its ratio to the test material calculated.

TIMETABLE

This study was performed on 07/16/2018.

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

The results are shown on the table below. Additionally, all raw data (individual specimen RDA values), the mean, the standard deviation, and standard error of the mean are reported on the attached table.

SUMMARY OF RELATIVE DENTIN ABRASION DATA ON TOOTH POWDER

Test Article	Relative Dentin Abrasion
LOVESMILES NATURAL ACTIVATED COCONUT SHELL CHARCOAL	54.54 ± 6.56*

* Mean ± SEM (N=8)

¹ Product mixing instructions reference: Pascaretti-Grizon F, Mabileau G, Chappard D. Abrasion of 6 dentifrices measured by vertical scanning interference microscopy. J Appl Oral Sci. 2013 Sep-Oct;21(5):475-81.

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 reports were submitted to the Study Director as follows:

<u>Phase</u>	<u>Date</u>
Data Audit	7/20/2018
Draft Report Review	7/20/2018
Report to Study Director and Management	

This Final Report accurately reflects the raw data.

QUALITY ASSURANCE



Robin Johnson, RHIA
Quality Assurance Manager

7/20/2018

Date

Relative Dentin Abrasion
Calculations By Weight
Study # **18-RDA-93**

LoveSmiles Pty Ltd
LOVESMILES NATURAL ACTIVATED
COCONUT SHELL CHARCOAL

1	51.54
2	53.45
3	43.83
4	32.44
5	48.03
6	42.05
7	78.38
8	86.60
Mean	54.54
Std. Dev.	18.55
Std. Err.	6.56

Ro Ding
7/16/2018