INDIANA UNIVERSITY
SCHOOL OF DENTISTRY
Oral Health Research Institute
IUPUI

FINAL REPORT # 17-RDA-185

TITLE
DETERMINATION OF THE RELATIVE DENTIN ABRASION LEVEL OF DENTIFRICES

STUDY SPONSOR
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PURPOSE
The purpose of this study was to determine the relative abrasion level of 13 dentifrices.

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 ($Ca_2P_2O_7$) 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 products were provided and coded by the Sponsor. The Sponsor is responsible for the identity, strength, purity, and composition or other characteristics of the test products. The products tested in this study were assigned to groups by the OHRI technician and labeled as follows:

Group	Sample Number	Product
A	Sample #1	R.O.C.S. Bold Blast of Double Mint
B	Sample #2	R.O.C.S. PRO Electro&Whitening
C	Sample #3	R.O.C.S. PRO Young&White Enamel
D	Sample #4	R.O.C.S. Teens Chocolate mousse
E	Sample #5	R.O.C.S. Kids Fruity cone
F	Sample #6	R.O.C.S. Caribbean Summer
G	Sample #7	R.O.C.S. Active calcium
H	Sample #8	R.O.C.S. Biocomplex
I	Sample #9	R.O.C.S. Amber 1
J	Sample #10	R.O.C.S. Amber 2
K	Sample #11	R.O.C.S. Amber 3
L	Sample #12	R.O.C.S. Dental polishing
M	Sample #13	R.O.C.S. PRO Sweet Mint

MATERIALS AND METHODS

Specimen Preparation

Eight (8) human dentin specimens were subjected to neutron bombardments resulting in the formation of radioactive phosphorus (^{32}P) 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 (25 g product/40 ml water) each tooth set was brushed with the ADA Reference Material (10g of $Ca_2P_2O_7$/50ml 0.5% CMC). The procedure was repeated additional times so that each 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 were 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.

DATA MANAGEMENT AND ANALYSIS

Data was analyzed using Kruskal-Wallis one-way analysis of variance on Ranks model [Sigma Plot (12.0) Software]. Since significant differences were found, additional all pair wise comparisons were done using the Student-Newman-Keuls method. All analyses were done with the significance level set at 0.05.

TIMETABLE

This study was conducted during 01/23-24/2018.

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.

COSTS

The cost for this study is $6,110 USD.

RESULTS AND CONCLUSIONS

The results are shown on the table below. Additionally, all raw data (individual specimen RDA values), the mean, the standard deviations, and standard errors of the mean for each group are reported on the attached tables.

Sample # 12, Sample# 7, Sample# 1, Sample# 8, Sample #13 were more abrasive than the remaining products.
Sample# 6 was more abrasive than Sample# 2 Sample# 3 and Sample# 4.
Sample 5 was more abrasive than Sample# 11, Sample# 10, and Sample# 9, the least abrasive.

SUMMARY OF RELATIVE DENTIN ABRASION DATA ON DENTIFRICES

Test Article	Test Product	Median		Relative Dentin Abrasion
Sample# 12	R.O.C.S. Dental polishing	106.09	**	105.78 ± 3.31*
Sample# 7	R.O.C.S. Active calcium	102.39		98.60 ± 5.02
Sample# 1	R.O.C.S. Bold Blast of Double Mint	101.55		97.87 ± 4.55
Sample# 8	R.O.C.S. Biocomplex	97.04		91.79 ± 5.57
Sample# 13	R.O.C.S. PRO Sweet Mint	93.58		93.81 ± 2.14
Sample# 6	R.O.C.S. Caribbean Summer	81.90		83.14 ± 2.44
Sample# 2	R.O.C.S. PRO Electro&Whitening	67.61		67.90 ± 2.89
Sample# 3	R.O.C.S. PRO Young&White Enamel	61.84		60.91 ± 2.67
Sample# 4	R.O.C.S. Teens Chocolate mousse	60.48		61.34 ± 3.46
Sample# 5	R.O.C.S. Kids Fruity cone	52.42		51.96 ± 1.73
Sample# 11	R.O.C.S. Amber 3	14.57		14.14 ± 1.31
Sample# 10	R.O.C.S. Amber 2	13.34		13.66 ± 1.29
Sample# 9	R.O.C.S. Amber 1	12.74		12.84 ± 0.83

* Mean ± SEM (N=8)
** Brackets denote no significant difference between groups (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

1-29-18

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

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:

Phase	Date
Data Audit	1/25-26/2018
Draft Report Review	1/26/2018
Report to Study Director and Management	1/26/2018

This Final Report accurately reflects the raw data.

QUALITY ASSURANCE

1/26/2018

Robin Johnson, RHIA
Quality Assurance Manager

Date

Relative Dentin Abrasion
Calculations By Weight
Study # **17-RDA-185**

WDS

	Sample #1	Sample #2	Sample #3	Sample #4	Sample #5	Sample #6
1	95.09	58.47	51.53	48.20	52.46	78.07
2	72.57	60.69	50.88	50.01	49.89	82.24
3	86.86	61.26	59.63	62.94	53.43	82.70
4	105.22	60.98	63.63	57.56	42.21	79.47
5	112.62	73.96	61.85	58.02	53.73	75.49
6	101.62	76.66	61.82	67.09	52.39	87.97
7	107.48	74.42	74.90	70.73	51.73	81.55
8	101.46	76.76	63.07	76.15	59.85	97.59
Mean	97.87	67.90	60.91	61.34	51.96	83.14
Std. Dev.	12.87	8.17	7.56	9.78	4.89	6.90
Std. Err.	4.55	2.89	2.67	3.46	1.73	2.44

Ro Ding
1/23-24/2018

Sample #7	Sample #8	Sample #9	Sample #10	Sample #11	Sample #12	Sample #13
76.52	62.25	16.04	16.77	19.81	92.82	88.33
91.33	74.45	15.68	17.30	14.54	96.31	94.32
106.12	90.50	13.72	14.80	15.31	111.72	97.66
119.27	101.23	13.59	18.56	14.60	102.56	92.84
108.20	98.47	11.89	9.39	17.74	99.15	102.60
82.60	95.60	11.84	11.89	11.74	109.62	85.55
100.17	103.13	9.57	9.73	10.93	117.00	100.24
104.62	108.66	10.41	10.81	8.41	117.03	88.93
98.60	91.79	12.84	13.66	14.14	105.78	93.81
14.20	15.75	2.34	3.65	3.70	9.37	6.06
5.02	5.57	0.83	1.29	1.31	3.31	2.14