



INDIANA UNIVERSITY

SCHOOL OF DENTISTRY
Oral Health Research Institute
IUPUI

FINAL REPORT # 19-RDA-199

TITLE

DETERMINATION OF THE RELATIVE DENTIN ABRASION LEVEL OF DENTIFRICE

STUDY SPONSOR

LIMA & PERGHER S/A
AV. AIRTON BORGES DA SILVA 740 ,
UBERLANDIA - MG - CEP 38402-100 - BRAZIL

Attention: Mr. Alcir Amâncio

CONDUCTING AGENCY

Indiana University School of Dentistry
Oral Health Research Institute
415 Lansing Street
Indianapolis, Indiana 46202-2876
Website: <https://dentistry.iu.edu/research/oral-health-research-institute/index.html>

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

Research Technicians: Ro Ding

PURPOSE

The purpose of this study was to determine the relative abrasion level of 1 dentifrice.

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 Standard Reference Material ($\text{Ca}_2\text{P}_2\text{O}_7$) 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 Standard 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	Product
B	Bianco Carbon Detox Pro-Esmalte

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

Standard Reference Material¹ 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 Standard Reference Material (10g of Ca₂P₂O₇/50ml 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 Standard 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 Standard Reference Material was assigned a value of 100 and its ratio to the test material calculated.

TIMETABLE

This study was conducted on 12/23/2019.

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 \$ 969 USD.

RESULTS AND CONCLUSIONS

The results are shown on the following table, where RDA mean values (\pm Standard Error of the Mean) are listed in descending order (higher mean RDA values represent higher abrasion). Additionally, all raw data (individual specimen RDA values), the mean, the standard deviation, and standard error of the mean for each group are reported on the attached tables.

SUMMARY OF RELATIVE DENTIN ABRASION DATA ON DENTIFRICE

Dentifrice	Sample size (N=8)*	Relative Dentin Abrasion**
Bianco Carbon Detox Pro-Esmalte	7	57.61 \pm 2.97

* Missing value was due to rejection by Q-test.


** Mean \pm SEM

¹ The Standard Reference Material was obtained from a specific lot of Calcium Pyrophosphate provided by Odontex Inc. 3030 Campfire Dr., Lawrence, KS 66040, USA.

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

1/7/20

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
Data Audit
Draft Report Review
Report to Study Director and Management

Date
1/6/2020
1/6/2020
1/6/2020

This Final Report accurately reflects the raw data.

QUALITY ASSURANCE



Robin Johnson, RHIA
Quality Assurance Manager

1/6/2020

Date

Relative Dentin Abrasion
Calculations By Weight
Study # **19-RDA-199**

LIMA & PERGHER S/A

Biano Carbon Detox Pro-Esmalte

1	64.66
2	49.65
3	49.46
4	64.98
5	49.86
6	58.35
7	66.33
8	*
Mean	57.61
Std. Dev.	7.86
Std. Err.	2.97

Ro Ding
12/23/2019

Explanations for missing values:
* Rejection by the Q-Test



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FINAL REPORT # 19-REA-200

TITLE

DETERMINATION OF THE RELATIVE ENAMEL ABRASION LEVEL OF DENTIFRICES

STUDY SPONSOR

LIMA & PERGHER S/A
AV. AIRTON BORGES DA SILVA 740 ,
UBERLANDIA - MG - CEP 38402-100 - BRAZIL

Attention: Mr. Alcir Amâncio

CONDUCTING AGENCY

Indiana University School of Dentistry
Oral Health Research Institute
415 Lansing Street
Indianapolis, Indiana 46202-2876
Website: <https://dentistry.iu.edu/research/oral-health-research-institute/index.html>

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

Research Technicians: Ro Ding

PURPOSE

The purpose of this study was to determine the relative abrasion level of 1 dentifrice.

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 enamel. The abrasivity limit specified by the ISO 11609 at 4x that of the reference material ($\text{Ca}_2\text{P}_2\text{O}_7$) may be considered in the interpretation of the results of this test. Therefore, since the current protocol has assigned an arbitrary value of 10 to the reference material, the REA abrasivity limit is 40.

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	Product
A	Bianco Carbon Detox Pro-Esmalte

MATERIALS AND METHODS

Specimen Preparation

Eight (8) human enamel 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 5000 stroke, precondition run using slurry consisting of 10g

Standard Reference Material¹ 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 5000 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 Standard Reference Material (10g of Ca₂P₂O₇/50ml 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 was taken, 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 REA (relative enamel abrasion) for the test material. The ADA material was assigned a value of 10 and its ratio to the test material calculated.

TIMETABLE

This study was performed on 01/30/2020.

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 \$1,213 USD.

RESULTS AND CONCLUSIONS

The results are shown on the following table, where REA mean values (\pm Standard Error of the Mean) are listed in descending order (higher mean REA values represent higher abrasion). Additionally, all raw data (individual specimen REA values), the mean, the standard deviation, and standard error of the mean for each group are reported on the attached tables.

SUMMARY OF RELATIVE ENAMEL ABRASION DATA ON DENTIFRICES

Dentifrice	Sample size (N=8)	Relative Enamel Abrasion**
Bianco Carbon Detox Pro-Esmalte	8	2.19 \pm 0.17


** Mean \pm SEM

¹ The Standard Reference Material was obtained from a specific lot of Calcium Pyrophosphate provided by Odontex Inc. 3030 Campfire Dr., Lawrence, KS 66040, USA.

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

2/4/20

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
Data Audit
Draft Report Review
Report to Study Director and Management

Date
2/3/2020
2/3/2020
2/3/2020

This Final Report accurately reflects the raw data.

QUALITY ASSURANCE

Robin Johnson, RHIA
Quality Assurance Manager

2/3/2020

Date

Relative Enamel Abrasion
Calculations By Weight
Study # 19-REA-200

LIMA & PERGHER S/A

Bianco Carbon Detox Pro-Esmalte

1	1.81
2	2.68
3	2.26
4	2.82
5	1.70
6	1.63
7	2.71
8	1.93
Mean	2.19
Std. Dev.	0.49
Std. Err.	0.17

Ro Ding
1/30/2020