

Substantiation of izzo Whitening Claim

Background

Dark color of teeth/teeth discoloration may be caused by intrinsic or extrinsic stains or a combination of both.

There are 2 major approaches to removing the stains:

- the chemical mechanism using peroxides for tooth bleaching
- the mechanical mechanism using abrasives in prophylactic pastes and dentifrices to remove stains,

both resulting in a whitening effect.

Definition of Whitening

According to Li, “ **tooth whitening is the process that results in the teeth becoming whiter in perceived color, regardless of the means used.** Therefore, tooth whitening can include bleaching with peroxides and mechanical approaches to remove surface stains using professionally applied abrasive prophylaxis pastes as well as tooth brushing with a whitening dentifrice.” [1]

Izzo Whitening Mechanism

Izzo helps to whiten teeth by removing surface stains during polishing. The degree and amount of surface staining is individual. If a user has a significant amount of surface stains he/she could expect a noticeable improvement after several polishing rounds, until most of your surface stains are removed.

Tooth stain build-up occurs when chromophores from food and drinks bind to the protein pellicle layer on the enamel surface. Izzo Polishing Paste contains mild abrasives which help to remove stains during polishing.

Quantifying izzo’s polishing cup/polishing paste system Stain Removal Ability

Method Description

Stain removal ability is expressed in Pellicle Cleaning Ratio (PCR). A PCR test is a means of comparing stain removal ability against a reference abrasive agent or a benchmark product.

The idea behind the PCR test is as follows:

- Bovine teeth are stained with stain producing solutions (ex. a mixture of tea, coffee, mucin, and iron chloride)
- The degree of stain is measured the color of the stained surface (results expressed in records $L^*a^*b^*$ color parameters)
- Stained surfaces are then brushed (or, in izzo case polished) using an artificial brushing machine under specific conditions of load, speed, and duration, with a slurry of a dentifrice mixed with water.
- After brushing (or, in izzo case polishing) the $L^*a^*b^*$ parameters are re-measured and changes are calculated in terms of overall color change (ΔE).

- Mean ΔE values for each measurement are calculated and compared to the reference abrasive thereby yielding a PCR value, which may fall into low, medium or high categories.

$$\Delta E^* = \sqrt{(L^*_{\text{post}} - L^*_{\text{pre}})^2 + (a^*_{\text{post}} - a^*_{\text{pre}})^2 + (b^*_{\text{post}} - b^*_{\text{pre}})^2}.$$



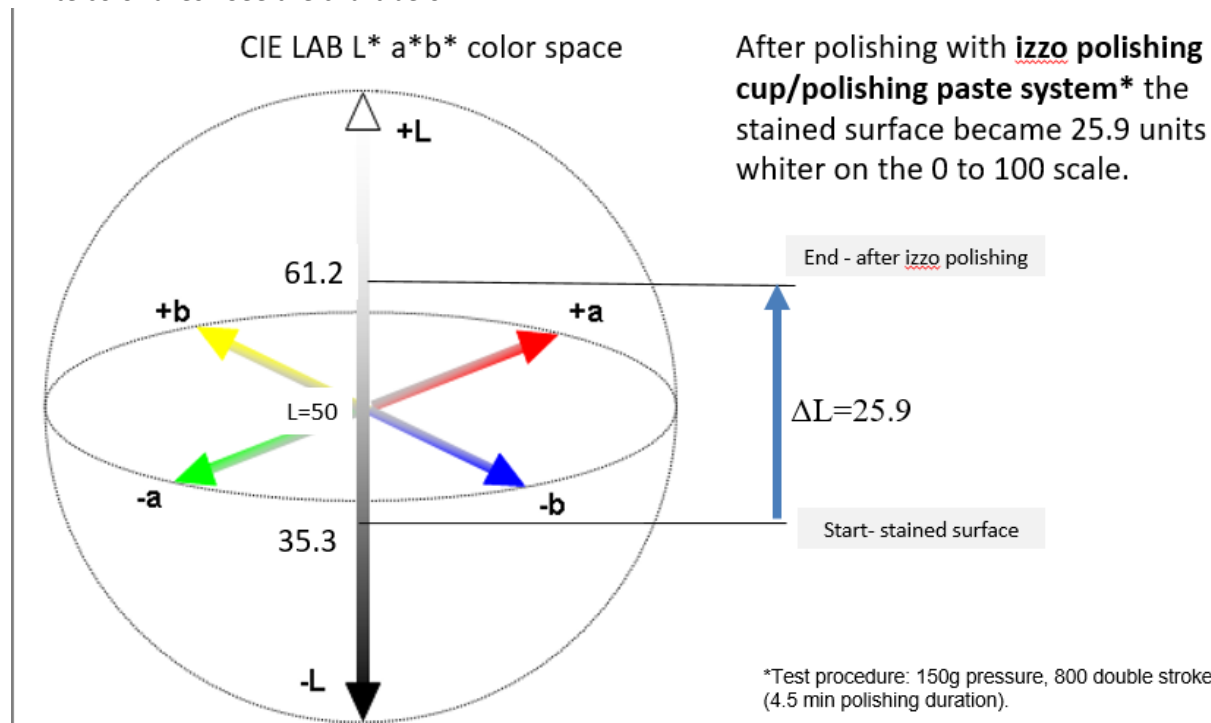
Illustration: Example - Stained bovine teeth surface before brushing or polishing
(Ref: <https://www.intertek.com/consumer-healthcare-trials/oral-care-pellicle-cleaning/>)

PCR test conducted on **izzo polishing cup/polishing paste system** was conducted by Therametric Technologies, Inc. Noblesville, IN. Specific details of the PCR test are described in the test protocol (attached).

Results

PCR test results on **izzo polishing cup/polishing paste system** are summarized in the PCR Study 21-266 Final Report (attached).

The results indicate that the color change for the izzo paste used in the final product (IZZO Prototype Formulation (Coarse)) corresponds to $\Delta E = 26.1 \pm 0.8$. It is important to point out that the greatest contributor to the ΔE value of 26.1 is ΔL (25.9), which describes the color change along the black-to-white color axes. See the chart below:



Izzo paste used in the final product (IZZO Prototype Formulation (Coarse)) is equivalent to a professional prophylaxis polishing at a dental office with a fine grit Prophy Paste (Enamel Pro Prophy Paste (Fine), $\Delta E = 25.1 \pm 1.0$). It is also 54% greater than the ISO/ADA reference standard $\Delta E = 16.9 \pm 0.6$.

PCR is calculated as the ratio of the ΔE of the sample to ΔE of the ISO/ADA reference standard. Thus, PCR of the standard is always 100. And izzo polishing cup/polishing paste system has the **PCR of 154.8 ± 4.5**

Colorimetric L*, a*, b* and ΔE^* Changes Following In Vitro Brushing Treatment

Treatment Group	ΔL^*	Δa^*	Δb^*	ΔE^*
ISO/ADA Reference Manual Toothbrush w/ ISO/ADA Reference Abrasive	16.8 \pm 0.6	-1.5 \pm 0.1 ^c	1.3 \pm 0.5 ^d	16.9 \pm 0.6
Power Prophy System w/ IZZO Prototype Formulation (Fine)	21.8 \pm 1.2	-1.7 \pm 0.1 ^{bc}	0.4 \pm 0.4 ^e	21.9 \pm 1.2
Power Prophy System w/ Premier Enamel Pro Prophy Paste (Fine)	24.9 \pm 1.0 ^a	-2.1 \pm 0.3 ^{ac}	0.6 \pm 0.6 ^e	25.1 \pm 1.0 ^a
Power Prophy System w/ IZZO Prototype Formulation (Coarse)	25.9 \pm 0.7 ^a	-2.2 \pm 0.1 ^b	1.3 \pm 0.7 ^e	26.1 \pm 0.8 ^a

* Mean (N=8) \pm SEM

** Values with same letter superscript do not differ significantly ($P \geq 0.050$) as determined by ANOVA / SNK analysis

Pellicle Cleaning Ratio (PCR) Values

Treatment Group	PCR Value
ISO/ADA Reference Manual Toothbrush w/ ISO/ADA Reference Abrasive	100.0 \pm 3.7
Power Prophy System w/ IZZO Prototype Formulation (Fine)	130.0 \pm 7.0
Power Prophy System w/ Premier Enamel Pro Prophy Paste (Fine)	148.7 \pm 6.1 ^a
Power Prophy System w/ IZZO Prototype Formulation (Coarse)	154.8 \pm 4.5 ^a

* Mean (N=8) \pm SEM

** Values with same letter superscript do not differ significantly ($P \geq 0.050$) as determined by ANOVA/SNK analysis

According to Putt *et al* study conducted by Indiana University-Purdue University [2], figure below compiles PCR values from various commercial dentifrices that are marketed for cleaning, whitening, and/or polishing capabilities. PCR data plotted in this chart is obtained by testing conducted by Therametric Technologies, Inc. Noblesville, IN [2]; it is the same laboratory that was used by Premier Dental to evaluate PCR of the izzo system.

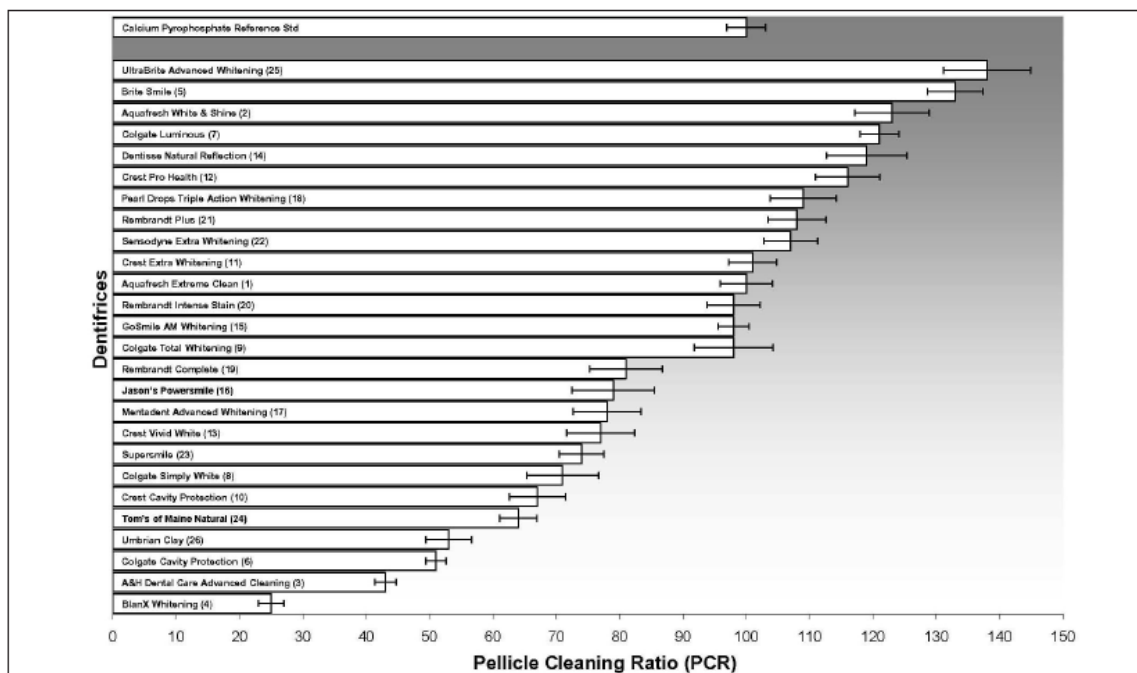


Figure 1. Pellicle Cleaning Ratio (PCR) data of commercial dentifrices ranked in order from lowest to highest stain removal. Dentifrices are labeled by tradename and identification number from Table I. Lengths of bars represent means; error bars show standard errors ($n = 16$).

According to the chart, the top three dentifrices with the highest PCR are:

Product	package label claim	Manufacturer	PCR
UltraBrite Advanced Whitening	Whitens Teeth	Colgate-Palmolive	139
Brite Smile	Whiten teeth safely and effectively	BriteSmile, Inc	133
Aquafresh White & Shine	Cleans and polishes for whiter, shinier teeth	GlaxoSmithKline	120

In addition, the average PCR (stain removal ability) of 26 advanced cleaning/whitening toothpastes from leading brands is 90. Thus, with PCR 155 izzo, **izzo polishing cup/polishing paste system is 73% better at removing stains than the average** of 26 advanced cleaning/whitening toothpastes from leading brands.

	Name	PCR
1	Aquafresh Extreme Clean	100
2	Aquafresh White & Shine	123
3	Arm & Hammer Dental Care Advanced Cleaning	43
4	BlanX Non-abrasive Whitening	25
5	Brite Smile	133
6	Colgate Cavity Protection	51
7	Colgate Luminous	121
8	Colgate Simply White	71
9	Colgate Total Whitening	98
10	Crest Cavity Protection	67
11	Crest Extra Whitening	101
12	Crest Pro-Health	116
13	Crest Vivid White	77
14	Dentisse Natural Reflection	119
15	GoSmile AM Whitening	98
16	Jason's Powersmile	79
17	Mentadent Advanced Whitening	78
18	Pearl Drops Triple Action	109
19	Rembrandt Complete	81
20	Rembrandt Intense Stain	98
21	Rembrandt Plus	108
22	Sensodyne Extra Whitening	107
23	Supersmile	74
24	Tom's of Maine Natural	64
25	UltraBrite Advanced Whitening	138
26	Umbrian Clay	53
	Competitive Average	90
	izzo	155
	% Increase	73%

Conclusion:

PCR value of izzo polishing cup/polishing paste is 155. It is higher than all 26 most common commercial dentifrices systems with whitening claims tested in Indiana University-Purdue University study.

In addition, izzo polishing cup/polishing paste system is 73% better at removing stains than the average of 26 advanced cleaning/whitening toothpastes from leading brands.

The data illustrates that the izzo system has the strongest stain removal ability, thus the greatest potential to whiten teeth.

References:

1. Li, Yiming, *Stain removal and whitening by baking soda dentifrice*, The Journal of the American Dental Association, Volume 148, Issue 11, S20 - S26 [https://jada.ada.org/article/S0002-8177\(17\)30811-5/fulltext](https://jada.ada.org/article/S0002-8177(17)30811-5/fulltext)
2. Putt, M. S., Schemehorn, B. R., Moore, M. H. *Abrasion, polishing, and stain removal characteristics of various commercial dentifrices in vitro*, The Journal of Clinical Dentistry, 2011; 22(1):11-8