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Labeled vs Actual Concentration of Bleaching Agents

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Clinical Relevance

Actual bleaching agent concentration needs to be what is indicated on the label. This study evaluates the differences in label vs. actual concentration of bleaching agents in dentist dispensed and over the counter products in four countries.

SUMMARY

The purpose of this study was to determine if the actual concentration of bleaching agents available in four different countries were the same as the label indicated and within the recommendations of the International Standard on Tooth Whitening. The method recommended for assaying peroxide by the United States Pharmacopeia was used to determine concentrations. All products in the United States and China were within the standard when products were tested immediately upon delivery at testing sites. One product in Saudi Arabia and three products in Brazil had greater than 30% concentration loss. Three of 24 products in the United States did not meet the International Standard when they were tested at month of expiration.

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DOI: http://dx.doi.org/10.2341/11-367-L

INTRODUCTION

Tooth whitening has become a $1.2 billion industry. Patients are requesting bleaching procedures at an ever-increasing rate and desire results as quickly as possible. Dentists are aware that rapidity and degree of whitening are dependent on many variables, including contact time and concentration of the active ingredient.

Studies[1,2] have documented discrepancies between the listed and actual concentrations of the active material in bleaching products. The concentration of bleaching agents in previously assayed products has varied from 1.08 above to 3.55 below the posted

concentration. Until recently, the difference in concentration was reported as a difference from the posted label concentration. The current standard for indicating differences in listed and actual bleaching agent concentrations is to indicate the percentage loss from the label concentration. A recently established International Standard for Bleaching Products requires that the actual concentration of active ingredient "shall not exceed 10% or lower than 30% of the manufacturer's stated concentration" over the stated lifetime of the products.[3]

The purpose of this current study was to gather tooth-whitening agents from four different parts of the world and to determine their concentrations and if the bleaching agents in the United States were within the recommendations of the International Standard at the month of expiration. Differences from the labeled concentration may occur during manufacturing, shipping, or storage of the tooth-whitening agents. Refrigeration during transportation from the manufacturer to dentist's office, when recommended, may vary from the manufacturer's recommendations, causing a more rapid degradation of the agents. This present study examines the labeled vs measured levels of active bleaching agents in tooth-whitening products prescribed by dentists or available over the counter in China, Brazil, Saudi Arabia, and the United States. The date of manufacture was unknown for the bleaching products tested; however, all tests were accomplished shortly after the products were received by the institutions conducting the testing.

The International Standard requires that products retain a certain percentage of the concentration indicated on the label until the date of expiration. The initial evaluation was accomplished when products were acquired to determine why some products may be less effective than expected. The evaluation at product expiration was performed to determine if the use life of the agents was within the requirement of the International Standard.

METHODS AND MATERIALS

An undergraduate student wrote to all the manufacturers of tooth-whitening agents available in the United States, requesting they forward a sample of each of their products for a comprehensive photo of commercially available bleaching products. Three months were spent collecting products. Thirty-five products were received, and they were stored at room temperature after arrival at the university. The over-the-counter products were purchased at local retailers. All assays to determine the initial concentration were performed by the end of the three months. The products were maintained at room temperature in the United States. Another student determined the concentration of the products on the month of expiration. Twenty-four of the products were available for assaying at that time. In China, Saudi Arabia, and Brazil, all products that were available in their countries were purchased and kept at room temperature until they were assayed. The various participants were able to collect 13 products in China, 7 products in Saudi Arabia, and 15 products in Brazil.

The same method of determining the amount of peroxide in the agents was used at all testing sites, which is the one recommended by the United States Pharmacopeia[4] and the International Standard.[3] The specific steps in this chemical analysis have been used in multiple studies.[5–9] The testing sites were sent the specific steps and asked to become familiar with the procedure. All of the participants who performed the tests are published authors in tooth whitening.

Prior to determining the amount of peroxide in a bleaching agent, a researcher at each site indicated on a data sheet the current date, manufacturer, product, expiration date, peroxide type, peroxide concentration, and trial number. An empty 250-mL beaker was then weighed on a scale that was accurate to three decimal points. Approximately 2 g of the bleaching product was placed in the empty beaker, and another weight was taken. The sample weight was calculated by subtracting the empty beaker weight from the beaker with the sample.

Deionized water was added to the 100-mL mark on the beaker. A stir bar was added, and the beaker was allowed to mix on a stir plate until a homogeneous mixture was attained. Twenty milliliters of glacial acetic acid was added, and the beaker was immediately covered with a watch glass. Approximately 2 g of potassium iodide was added to the solution and allowed to dissolve, which turned the solution to a light shade of yellow. Three drops of ammonium molybdate were added, and the solution was allowed to again become homogenous. The beaker was then transferred to a darkened cupboard. The darkened cupboard was used to allow the chemicals to fully associate to ensure complete reaction with the available peroxide agent.

Once the sample had been in a darkened area for at least 10 minutes, it was placed on the stir plate. Gradually, 0.025 N sodium thiosulfate was triturated into the solution, using a 50-mL burette, until the

Table 1: *Bleaching Agents Available to Dentists Only in the United States Listed by Manufacturer, With Lot Number, Type of Peroxide, Label Concentration, Average Concentration, and Concentration Difference (cont.)*

Manufacturer	Product	Lot No.	Pr Ty	Label Conc	Average	% Diff
Agents with concentrations within 15% of label						
Spectrum Dental	Contrast AM	06192010	HP	22.00	23.33	6.00
Discus Dental	Night White ACP	6208022	CP	22.00	23.15	5.20
Premier	Perfecta Rev	2547	HP	14.00	14.49	3.50
Premier	Dental Whitening Systems	16062006	CP	16.00	16.47	2.90
Premier	Perfecta Ultra	2265	HP	6.00	6.17	2.80
Discus Dental	Night White ACP	6219081	CP	10.00	10.22	2.70
Discus Dental	Night White Excel 3 Turbo	6213074	HP	6.00	6.11	1.80
Temrex	Star White	11168-0306	CP	16.00	16.26	1.60
Premier	Dental Whitening Systems	11042706	CP	11.00	11.09	0.80
Ivoclar Vivadent	Vivastyle Touch Up	JL1017	CP	10.00	10.07	0.70
Ultradent Products	Opalescence PF10	B2HNF	CP	10.00	9.96	0.40
Patterson Dental	Tooth Whitening Gel	B26KS	CP	16.00	16.03	0.20
Ultradent Products	Opalescence	B27BN	CP	10.00	9.90	−1.00
Nu Radiance	Nu Radiance Touch-up Kit	060613–0900	CP	16.00	15.83	−1.10
SDI	Pola Day	68454	HP	7.50	7.32	−2.40
Spectrum Dental	Contrast PM	6181007	CP	15.00	14.58	−2.80
Ultradent Products	Opalescence PF15	B283D	CP	15.00	14.47	−3.50
Dentsply	Nupro White Gold	60718	CP	15.00	14.38	−4.10
Ivoclar Vivadent	Vivastyle Plus	JL1017	CP	10.00	9.57	−4.30
Ultradent Products	Opalescence PF20	B25V3	CP	20.00	19.02	−4.90
Discus Dental	Day White	6226026	HP	9.50	9.00	−5.30
Spectrum Dental	Contrast PM	6180014	CP	10.00	9.41	−5.90
Premier	Perfecta	B27GZ	CP	16.00	14.97	−6.40

Table 1: Continued.

Manufacturer	Product	Lot No.	Pr Ty	Label Conc	Average	% Diff
Premier	Perfecta Bravo	2493	HP	9.00	8.36	−7.10
Premier	Perfecta	B27GZ	CP	11.00	10.12	−8.00
Premier	Perfecta	B27GZ	CP	13.00	11.86	−8.80
Patterson Dental	Tooth Whitening Gel	B26KT	CP	22.00	20.07	−8.80
Spectrum Dental	Contrast PM	6165030	CP	15.00	13.58	−9.50
Premier	Perfecta	B251Q	CP	21.00	18.92	−9.90
SDI	Pola Night	60405	CP	16.00	14.41	−10.00
SDI	Pola Night	68400	CP	22.00	19.59	−11.00
Patterson Dental	Tooth Whitening Gel	B09N8	CP	11.00	9.38	−14.70
Agents with concentrations between 15% and 30% lower than label indicates						
Discus Dental	Night White ACP	6205027	CP	16.00	13.32	−16.80
SDI	Pola Paint	51220	CP	8.00	6.65	−16.90
Discus Dental	Day White	6215024	HP	7.50	5.50	−27.00

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.

sample turned a pale shade of yellow. Three milliliters of a 1.0% starch indicator was added to the solution, turning the solution a dark purple. More sodium thiosulfate was titrated into the solution, using a 10-mL burette, until the solution turned colorless, which was the end point of the assay. All chemical analyses of concentrations were performed in triplicate.

The concentration of the bleaching agent was determined by the following formula:

$$\text{Hydrogen Peroxide (HP)\%} = 1.704 \times \text{TSmL} \times (0.025/\text{PWg})$$

$$\text{Carbamide Peroxide (CP)\%} = 4.704 \times \text{TSmo} \times (0.025/\text{PWg})$$

where TS is sodium thiosulfate and PW is product weight.

RESULTS

United States

Thirty-two products dispensed to dentists were within 15% of the active agent concentration listed on the label (Table 1). Three products had a 15% lower but not more than a 30% lower concentration of active agent than that listed on the label. All of the tooth-whitening agents dispensed to dentists in the United States that were assayed in this study were within the requirements established by the International Standard upon delivery to the testing site.

In the United States, the concentration of the active agent in the bleaching products available over the counter was also assayed. Manufacturers are not required by the Food and Drug Administration to list the active agent concentration of cosmetic products, only to list the ingredients found in the product. The new International Standard requires manufacturers of all tooth-whitening products to list

Table 2: *Over-the-Counter Bleaching Agents in the United States Listed by Manufacturer, With Lot Number, Type of Peroxide, and Average Concentration*

Manufacturer	Product	Lot No.	Pr Ty	Label Conc	Average
Lumalite	GentleBright Plus	6C091/6C101	HP	None	0.94
Lumalite	StayBright Plus	F609060	HP	None	7.30
Nu Radiance	Duet 30	060524–0800	CP	None	12.62
Nu Radiance	Forte with Calcium	060424–1300	CP	None	22.70
Procter & Gamble	Crest Whitening Rinse	95659415	HP	None	1.54
Proctor & Gamble	Crest Night Effects Gel	61525614TO	HP	None	3.33
Proctor & Gamble	Crest Strips Premium Plus 10 day	625BT4	HP	None	9.29
Proctor & Gamble	Crest Whitestrips Classic 14 day	6221BT2	HP	None	6.18
Proctor & Gamble	Crest Whitestrips Premium	6254BT4	HP	None	9.77
Proctor & Gamble	Crest Whitestrips Renewal 10 day	6017BT2	HP	None	7.93
Proctor & Gamble	Crest Whitestrips Daily Multicare	7180BT3	HP	None	6.07
TeleBrands	White Light	WLPGR5D	CP	None	21.22
Plus White	5 Min Speed Whitening	7610	HP	None	6.06
Oral B	Rembrandt 2hr White	266057	HP	None	6.12
GlaxoSmithKline	Aquafresh White Trays	6L11C1	HP	None	10.32
Dentco	Equate Dental Whitening Strips	7E03A	CP	None	10.02
Johnson & Johnson	Rembrandt 2hr Whiten Kit	0887AR290874	HP	None	5.70

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.

the concentrations of the active bleaching agent on the packaging. Since the products were not required to identify the concentration on the label, it was not possible to identify the concentration differences at the time of testing. The over-the-counter product concentrations of carbamide peroxide (CP) ranged from 10% to 23% CP, and the hydrogen peroxide (HP) concentrations ranged from .09% to 10% HP (Table 2).

Twenty-four products were tested at the month of expiration. Three products were found to have concentrations less than that accepted by the International Standard (Table 3).

China

The concentration testing for the tooth-whitening agents that were available on the Chinese market was accomplished at Wuhan University in Wuhan, China. Thirteen products were secured and assayed. Nine of the products had CP as the active agent, with agent concentrations ranging from 8% to 19% CP. Four of the products had HP as the active agent,

Table 3: *Bleaching Agents in the United States Assayed During the Month of Expiration, Listed by Manufacturer, With Lot Number, Type of Peroxide, Label Concentration, Mean Concentration of Three Trials, and Concentration Difference*

Manufacturer	Brand Name	Lot No.	Type	Label Conc	Mean Conc	% Difference
Premier	Perfecta Bravo	2493	HP	9.00	9.14	2
Spectrum Dental	Contrast AM	06192010	HP	22.00	22.07	0
Ultradent Products	Opalescence PF10	B2HNF	CP	10.00	9.96	0
Discus Dental	Night White Excel 3 Turbo	6213074	HP	6.00	5.79	−4
Premier	Dental Whitening Systems	11042706	CP	11.00	10.08	−8
Ultradent Products	Opalescence PF20	B25V3	CP	20.00	18.22	−9
Discus Dental	Day White	6215024	HP	7.50	6.77	−10
Discus Dental	Night White ACP	6205027	CP	16.00	14.22	−11
Discus Dental	Night White ACP	6219081	CP	10.00	8.82	−12
SDI	Pola Day	68454	HP	7.50	6.50	−13
Discus Dental	Night White ACP	6208022	CP	22.00	18.93	−14
Patterson Dental	Tooth Whitening Gel	B26KS	CP	16.00	13.72	−14
Premier	Dental Whitening Systems	16062006	CP	16.00	13.81	−14
Premier	Perfecta Ultra	2265	HP	6.00	5.89	−14
Agents with concentrations between 15% and 30% lower than label indicates						
Ultradent Products	Opalescence	B27BN	CP	10.00	8.42	−16
Dentsply	Nupro White Gold	60718	CP	15.00	12.32	−18
Premier	Perfecta	B27GZ	CP	11.00	8.82	−20
Patterson Dental	Tooth Whitening Gel	B26KT	CP	20.00	17.50	−22
SDI	Pola Paint	51220	CP	8.00	0.26	−26
SDI	Pola Night	68400	CP	22.00	15.96	−27
Spectrum Dental	Contrast PM	6165030	CP	15.00	10.76	−28
Agents with concentrations more than 30% lower than label indicates						
Spectrum Dental	Contrast PM	6180014	CP	10.00	7.05	−30
Discus Dental	Day White	6226026	HP	9.50	6.36	−33
Spectrum Dental	Contrast PM	6181007	CP	15.00	9.60	−36

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.

Table 4: *Bleaching Agents in China Listed by Manufacturer, With Product Name, Type of Peroxide, Label Concentration, Average Concentration, and Concentration Difference*

Manufacturer	Product	Pr Ty	Label Conc	Average	% Diff
Agents with concentrations within 15% of label					
*Kernel Bio Tech	Whitening Strip (16 CP)	CP	16	17.34	8.4
*CCA	Plus White (6 HP)	HP	6	6.27	4.5
Ultradent	Opalescence (10 CP)	CP	10	10.24	2.4
*Crest	Whitestrips Premium (10 HP)	HP	10	10.19	1.9
Ultradent	Opalescence (20 CP)	CP	20	19.19	−4
Ultradent	Confi-white Tooth whitening Gel (15 CP)	CP	15	14.38	−4.1
Ultradent	Opalescence (15 CP)	CP	15	14.01	−6.6
Ultradent	Confi-white Tooth whitening Gel (10 CP)	CP	10	9.28	−7.2
Discus Dental	Nite White (9.5 HP)	HP	9.5	8.79	−7.5
*Onuge	Professional Whitening strip (10 CP)	CP	10	9.13	−9.7
Agents with concentrations between 15% and 30% lower than label indicates					
*AWG	Teeth Whitening Gel (8 HP)	HP	8	6.69	−16.4
Discus Dental	Nite White (10 CP)	CP	10	8.27	−17.3
*Onuge	Dental Whitening Strip (8 CP)	CP	8	6.56	−18

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.
** Products available over-the-counter.*

with agent concentrations ranging from 6-10% HP. Six of the products were available over the counter, and the other seven were available from dental offices. Ten of the products were within 15% of the concentration on the label. Three products had concentrations that were lower than 15% of the indicated concentration but were not more than 30% lower than the listed active agent concentration on the label (Table 4).

Brazil

The concentration testing for the bleaching products that were available on the Brazilian market was accomplished at the University of Santa Catarina in Florianopolis, Brazil. Fifteen products were secured and assayed. Twelve of the products contained CP and had concentrations ranging from 9% to 37% CP. Three of the products contained HP and had concentrations ranging from 6% to 7.5% HP. No tooth-whitening products were available over the counter. Six of the products were within 15% of the concentration on the label. Six products had concentrations that were lower than 15% of the indicated concentration but were not more than 30% lower than the listed concentration of the active agent. Three of the products had a loss of more than 30% of the concentration indicated on the label (Table 5).

Table 5: *Bleaching Agents in Brazil Listed by Manufacturer, With Product Name, Type of Peroxide, Label Concentration, Average Concentration, and Concentration Difference*

Manufacturer	Product	Pr Ty	Label Conc	Average	% Diff
Agents with concentrations within 15% of label					
Ultradent Products	Opalescence PF (15 CP)	CP	15	13.86	−7.6
Ultradent	Opalescence PF (20 CP)	CP	20	18.26	−8.7
Voco	Perfect Bleach (10 CP)	CP	10	9.02	−9.8
SS White	Review 16F (16 CP)	CP	16	14.22	−11.1
FGM	White Class (7.5 HP)	HP	7.5	6.61	−11.9
Villevie	Mix Day (6 HP)	HP	6	5.27	−12.2
Agents with concentrations between 15% and 30% lower than label indicates					
Ultradent	Opalescence PF (10 CP)	CP	10	8.42	−15.8
FMG	Whiteness Standard (10 CP)	CP	10	7.26	−17.4
FGM	White Class (6 HP)	HP	6	4.93	−17.8
FGM	Whiteness Standard (16 CP)	CP	16	12.51	−21.8
Vigodent	Whiteness Perfect (16 CP)	CP	16	11.6	−27.50
FGM	Magic Bleaching (16 CP)	CP	16	11.38	−28.9
Agents with concentrations more than 30% lower than label indicates					
Vigodent	Magic Bleaching (10 CP)	CP	10	6.66	−33.4
SSWhite	Review 10F (10 CP)	CP	10	5.59	−44.1
Vigodent	Magic Bleaching (37 CP)	CP	37	18.33	−50.5

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.

Saudi Arabia

The concentration testing for the bleaching agents that were available on the Saudi Arabian market was accomplished at King Saud University in Riyadh, Kingdom of Saudi Arabia. Seven products were secured and assayed. The labels indicated that six of the products contained CP and had concentrations ranging from 10–22% CP; one of the products contained HP, and the label indicated a 7.5% HP concentration of the active agent. No tooth-whitening products were available over the counter. One of the products was within 15% of the concentration on the label. Five products had concentrations that were lower than 15% of the indicated concentration but were not more than 30% lower than the listed concentration of active agent. One of the products had a loss of more than 30% of the concentration indicated on the label (Table 6).

Table 6: *Bleaching Agents in Saudi Arabia Listed by Manufacturer, With Product Name, Type of Peroxide, Label Concentration, Average Concentration, and Concentration Difference*

Manufacturer	Product	Pr Ty	Label Conc	Average	% Diff
Agents with concentrations within 15% of label					
Ultradent Products	Opalescence (10 CP)	CP	10	9.17	−8.3
Agents with concentrations between 15% and 30% lower than label indicates					
Ultradent	Opalescence PF (20 CP)	CP	20	16.26	−18.7
Discus Dental	Nite White (16 CP)	CP	16	12.71	−20.6
Discus Dental	Nite White (22 CP)	CP	22	17.03	−22.6
Ultradent Products	Opalescence PF (15 CP)	CP	15	11.36	−24.3
Discus Dental	Nite White (10 CP)	CP	10	7.41	−25.9
Agents with concentrations more than 30% lower than label indicates					
Discus Dental	Day White (7.5 HP)	HP	7.5	4.62	−38.4

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.

DISCUSSION

It is well accepted that bleaching effectiveness depends on the time the agent is in contact with the teeth and on the concentration of the agent. The *Clinical Research Associates Newsletter* has stated that "storage for extended time or in warm temperature, faulty packaging, and other problems can cause bleaches to lose potency."[9] The Clinical Research Associates performed their study using a different assay methodology. Of the 12 products they assayed, eight were within 1 of the concentration indicated on the label. Four products were more than 1 higher than the label indicated, and one product was more than 1 lower than the label indicated.

Previous studies in which concentrations were assayed evaluated products as a combined total of all similar products by specific manufacturers and not as individual products. In a report in 2000, the mean decrease in the concentrations of 10%, 15%, and 20% in Contrast PM products was 3.55 less than the label indicated. Rembrandt products of 10%, 15%, and 22% were 1.08 higher than the label indicated.[1] In a report published in 2003, Stark White products of 10%, 16%, and 22% were found to be 2.64 less than the label indicated.[2]

In Brazil, tooth-whitening agents are required to put the date the product was manufactured, instead of the lot number, on the label. The manufacturing date was not evident on the products in the other countries. It is possible to use the lot number to determine the time of production by contacting the manufacturer, if there is a need to know that at some point in time.

In the past, the consumer had no way of knowing the concentration of active agents in the products sold over the counter in the United States. The International Organization of Standardization now requires manufacturers to list the concentrations of active agents on all tooth-whitening agents. Patients are now able to make an informed decision as to the concentration of over-the-counter products they are purchasing.

Manufacturers have a responsibility to deliver products to the dental practitioner with the bleaching agent concentrations that are listed on the label. It is known that HP is not as stable as CP. The urea in CP stabilizes the HP. HP degrades less rapidly in cold and away from sunlight. Dental practitioners

need to keep the products that recommend refrigeration in a cool area to lower the rate of degradation before use.

Manufacturers need to review the expiration dates they place on tooth-whitening agents to ensure the product they market remains within the labeled concentration required by the International Organization of Standardization. Universities around the world need to assay tooth-whitening agents and publish the results in their national dental journals to indicate which ones are at lower concentration than the label indicates at the time of delivery and those that are within the standard at the month of expiration. This will encourage manufacturers to reevaluate the priority they place on maintaining concentrations of products at the appropriate level.

Manufacturers need to adjust the expiration dates, place another agent in the active agent to reduce the degradation of their products, or encourage dental practitioners to keep their products in a cool place so the products will be at the full strength indicated on the label when patients use their products. This will give practitioners the confidence to expect predicted results.

CONCLUSION

The tooth-whitening products available in the United States and China were all within the newly established International Standard. One product in Saudi Arabia and three products in Brazil had a loss of at least 30% or more of the concentration indicated on the label by the manufacturer. These products were assayed after securing the products in the respective country. When testing was accomplished at the month of expiration in the United States, three products had a loss of more than 30% of the concentration indicated on the label. Products with a loss of at least 30% of the listed concentration at any time before the expiration date do not meet the International Standards for tooth-whitening agents.

Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

(Accepted 19 January 2012)

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