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A Clinical Evaluation of Bleaching Using Whitening Wraps and Strips

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Clinical Relevance

When used twice daily, Ranir Whitening Wraps were more effective in lightening teeth than Crest Whitestrips Premium when also used twice a day.

SUMMARY

This study evaluated the degree of color change of teeth and the sensitivities of teeth and gums in an *in vivo* study. Ranir Whitening Wraps (WW2) and Crest Whitestrips Premium (WP2) were used twice a day and Ranir Whitening Wraps (WW1) were used once a day. Color evaluations occurred at baseline, after five and seven-day use of bleaching agent and 14 days post-bleaching. Color change was evaluated objectively and sub-

jectively. Sensitivity evaluations were also accomplished. Seventy-six of the 78 subjects enrolled completed the study. All three products significantly lightened teeth. WW2 lightened more than WP2 and WW1 in L*, a*, b*, E and shade guide value. WP2 lightened more than WW1 in a*, b*, E and shade guide value. There was no difference in tooth sensitivity, but WW1 and WP2 caused less gingival sensitivity than WW2. The mean age of smokers was seven years younger than non-smokers who qualified.

INTRODUCTION

Cosmetic dentistry is a very important part of today's restorative dental practice. The appearance of teeth, health and fitness are increasingly important for patients of all ages. Cosmetic procedures have become more available for a majority of society, since standards of living have improved.

Dentistry has succeeded in reducing the frequency and severity of caries and periodontal disease, leading to the increased preservation of natural teeth throughout life. Since white teeth are believed to be associated with health and beauty, lighter colored teeth have become desirable and popular (Dunn, Murchison & Broome, 1996). Therefore, it is up to our profession to offer techniques and expertise that enables patients to safely achieve these goals. Vital tooth bleaching can be performed with a high rate of success and is a more

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conservative treatment for discolored teeth compared to restorative treatment such as porcelain veneers, crowns or composite bonding (Christensen, 2002).

Today, patients have the choice of having tooth bleaching done in two ways: in-office or at-home. In-office vital tooth bleaching has been used for many years in dentistry (Barghi, 1998). It lightens teeth rapidly, but the procedure is more time-consuming for the dentist, costs more for patients and the degree of tooth whitening is usually less than that accomplished with at-home tooth whitening agents used in trays.

At-home bleaching has traditionally involved the use of trays loaded with bleaching gel. However, new products have been introduced that use a different approach (Li & others, 2003). These products are wraps and strips, impregnated with tooth whitening agent, which patients can place against the facial surfaces of their teeth.

This study evaluated the ability of bleaching wraps and strips to lighten the color of teeth using three different methods. The study was also designed to evaluate sensitivities associated with bleaching methods.

METHODS AND MATERIALS

Before participating in this bleaching study, subjects signed a consent form. The form and the research protocol were approved by the Institutional Review Board at Indiana University-Purdue University Indianapolis (IUPUI).

The following criteria was used in subject recruitment and enrollment in the study:

Inclusion Criteria

1. Have all six maxillary anterior teeth.
2. Have no maxillary anterior teeth with more than 1/6 of the labial surface of the natural tooth covered with a restoration.
3. Be willing to sign a consent form.
4. Be at least 18 years of age.
5. Be able to return for periodic examinations.
6. Have maxillary anterior teeth that are between B-56 and D-85 shades on the Trubyte Bioform Color Ordered Shade Guide (Dentsply Int, York PA, USA).

Exclusion Criteria

1. History of any medical disease that may interfere with the study or require special considerations.
2. Current or previous use of professionally applied or prescribed "in-office" or "at-home" bleaching agents.
3. Gross pathology in the oral cavity (excluding caries).
4. Pregnant or lactating women.
5. Tetracycline-stained teeth.

If the patient met the criterion, a baseline appointment was made for the subject. At that appointment color evaluation was performed using two methods: 1) subjective shade guide matching of maxillary anterior teeth with Trubyte Bioform Color Ordered Shade Guide (Dentsply Int) and 2) by using an objective color measuring device (ShadeEye, Shofu, Inc, Kyoto, Japan). The authors constructed an intraoral jig to ensure the objective color-measuring device measured the same area for each subject at all evaluation appointments.

The colorimeter measures the color of teeth based on the CIE L*a*b* color space system. This system was defined by the International Commission on Illumination (1978) and is referred to as CIELAB. The L* represents the value (lightness or darkness), a* is the measurement along the red-green axis and b* is the measurement along the yellow-blue axis. A positive a* value indicates the red direction, a negative a* value the green direction, a positive b* value the yellow direction and a negative b* value the blue direction (Matis & others, 1999). At the end of the study, total color differences or distances between two colors (ΔE) were calculated using the formula:

$$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2} \text{ (International Commission on Illumination, 1978)}$$

A die was rolled to determine which procedure the non-smoking or smoking subjects received. If the die indicated 1 or 2, Whitestrips Premium (Procter & Gamble, Cincinnati, OH, USA) were to be used for 30 minutes, twice a day (WP2) for seven days. These strips contain 10% hydrogen peroxide gel. A 3 or 4 roll on the die indicated Whitening Wraps (Ranir Corporation, Grand Rapids, MI, USA) were to be used for 30 minutes, twice a day (WW2), for seven days. A five or six roll indicated Whitening Wraps (Ranir Corporation) were to be used for 30 minutes, once a day (WW1), for seven days. The Whitening Wraps that were evaluated contained 8% hydrogen peroxide gel. An assistant, not involved in any other part of the study, explained and demonstrated to the subjects how to use the various products according to the manufacturers recommended instructions. The subjects then left the clinic with the products in a non-identifiable bag.

The manufacturer of wraps recommends brushing immediately before applying their product, while the manufacturer of strips does not recommend brushing at that time. All subjects, however, were asked to brush at least twice daily to maintain a standardized home care regimen.

All subjects were provided a non-whitening dentifrice and a soft bristled manual toothbrush. They were also given a diary upon which they indicated on a daily basis the level of tooth and gum sensitivity that they experienced and the times during the morning and/or evening when they used the at-home wraps or strips. The active

Table 1: Demographics of Subjects

	Gender	Groups							
		All	(Age)	WP/2X	(Age)	WW/2X	(Age)	WW/1X	(Age)
All Subjects	Both	76	(53.4)	25	(55.1)	26	(52.1)	25	(53.0)
	Female	35	(53.7)	8	(55.3)	14	(55.8)	13	(50.4)
	Male	41	(53.1)	17	(55.0)	12	(47.8)	12	(55.8)
Non-smokers	Both	62	(54.9)	21	(56.2)	22	(53.6)	19	(54.9)
Smokers	Both	14	(46.6)	4	(49.2)	4	(43.8)	6	(47.0)

phase of the treatment lasted seven days. The subjects were asked to return to receive potassium nitrate desensitizing gel if their sensitivity was more than moderate.

The use of the strips and wraps was separated by at least three hours when required to be worn twice a day. The subjects returned in five and seven days after using the at-home bleaching strips and wraps for the same type of color evaluation conducted during the baseline evaluation. They also returned for a 14-day post-bleaching color evaluation.

RESULTS

Seventy-six of the 78 subjects enrolled completed the study. Thirty-five (46%) were female and 41 (54%) were male (Table 1). The Whitestrips Premium group had 25 subjects, Whitening Wraps 2 had 26 subjects and Whitening Wraps 1 had 25 subjects. The youngest and oldest subjects were 32 and 80, respectively. The mean age of the non-smokers was 55; the mean age of the smokers was 47 years of age. The study was open to smokers and non-smokers; however, only 18% of the subjects who qualified were smokers.

At baseline examinations, subjects from the WP2, WW2 and WW1 groups had mean L* values of 66.12, 66.55 and 65.93, respectively, which were not significantly different ($p=0.75$), a* values of 0.31, 0.45 and 0.34, respectively, which were not significantly different ($p=0.71$), b* values of 13.85, 14.08 and 14.60, respectively, which were not different statistically ($p=0.72$) and Trubyte Bioform shade values of 19.07,

Table 2: Mean Baseline Values for the Three Groups

Groups	Day	N	L*	a*	b*	Bioform
WP/2X	0	25	66.12	0.31	13.85	19.07
	5	24	68.07	-0.36	11.68	13.21
	7	25	68.37	-0.51	11.04	11.73
	21	25	67.89	-0.57	11.42	12.03
WW/2X	0	26	66.55	0.45	14.08	19.06
	5	26	69.15	-0.28	11.72	11.44
	7	26	69.47	-0.44	11.17	9.04
	21	26	68.88	-0.52	11.44	9.35
WW/1X	0	25	65.93	0.34	14.60	19.93
	5	24	67.43	-0.19	12.81	14.67
	7	25	67.89	-0.29	12.69	13.48
	21	25	67.71	-0.34	12.86	14.43

Table 3: Mean Change for the Three Groups

Groups	Day	N	ΔL*	Δa*	Δb*	ΔE	ΔBioform
WP/2X	0	25	0.00	0.00	0.00	0.00	0.00
	5	24	1.99	-0.69	-2.16	3.27	-5.84
	7	25	2.25	-0.82	-2.81	3.95	-7.33
	21	25	1.77	-0.88	-2.43	3.37	-7.04
WW/2X	0	26	0.00	0.00	0.00	0.00	0.00
	5	26	2.61	-0.73	-2.37	3.75	-7.63
	7	26	2.93	-0.88	-2.92	4.38	-10.03
	21	26	2.33	-0.97	-2.64	3.79	-9.59
WW/1X	0	25	0.00	0.00	0.00	0.00	0.00
	5	24	1.53	-0.47	-1.49	2.38	-5.26
	7	25	1.96	-0.63	-1.90	2.97	-6.45
	21	25	1.78	-0.67	-1.73	2.82	-5.51

19.06 and 19.93, respectively, which were not significantly different ($p=0.41$) (Table 2).

The color change in E and shade guide change are illustrated graphically in Figures 1 and 2, respectively. All three groups had significant mean changes from baseline to 14 days post-bleaching in ΔL*, Δa*, Δb*, ΔE and ΔTrubyte Bioform shade ($p<0.001$) (Table 3).

Subjects receiving the WW2 treatment had significantly different ΔL* ($p=0.0208$) and Δ shade guide ($p=0.0079$) values than did those subjects in the WP2 group. Subjects receiving the WP2 treatment had sig-

nificantly different Δa^* ($p=0.0029$), Δb^* ($p=0.0022$) and ΔE ($p=0.0063$) values than those receiving the WW1.

There were no differences among the three groups for tooth sensitivity ($p=0.42$). Regarding gum sensitivity, the WW2 group had significantly higher values than the WP2 ($p=0.0167$) and WW1 ($p=0.0362$) groups.

The objective color measurements indicate significantly different L^* ($p=0.0106$) and a^* ($p=0.0556$) change for non-smokers, while subjective color measurement indicated significantly different Trubyte shade guide ($p=0.0089$) change for smokers.

DISCUSSION

Whitening wraps and strips were evaluated in a single blind, three-week study with 78 subjects randomized into three equal cells balanced by product used and smoking versus non-smoking. The three cells consisted of 1) those using Whitening Wraps twice a day, 2) those using Whitening Wraps once a day and 3) those using Whitestrips Premium twice a day. Seventy-six subjects were evaluated at baseline, 5, 7 and 21 days using a colorimeter and a shade guide.

All groups had significant mean changes from baseline to 21 days for all color measurements. Some products were shown to be significantly different when comparing color change between them.

Subjects using WW2 were significantly lighter overall in tooth whitening than those using WP2 in L^* and shade guide value. Subjects using WW2 were significantly lighter overall in tooth whitening than those using WW1 in L^* , a^* , b^* , E and shade guide values.

Subjects using WP2 were significantly lighter overall in tooth whitening than those using WW1 in a^* , b^* , E and shade guide values. Subjects using WP2 were sig-

nificantly lighter overall in tooth whitening than those using WW1 in a^* , b^* and E .

There were no differences between groups for tooth sensitivities, however, subjects reported that WW2 caused significantly more gum sensitivity. Gum sensitivity seemed to occur much more frequently in subjects with shorter teeth, because placement of the rigid tray extended onto the tissues, causing rubbing of the tray on the gum tissues.

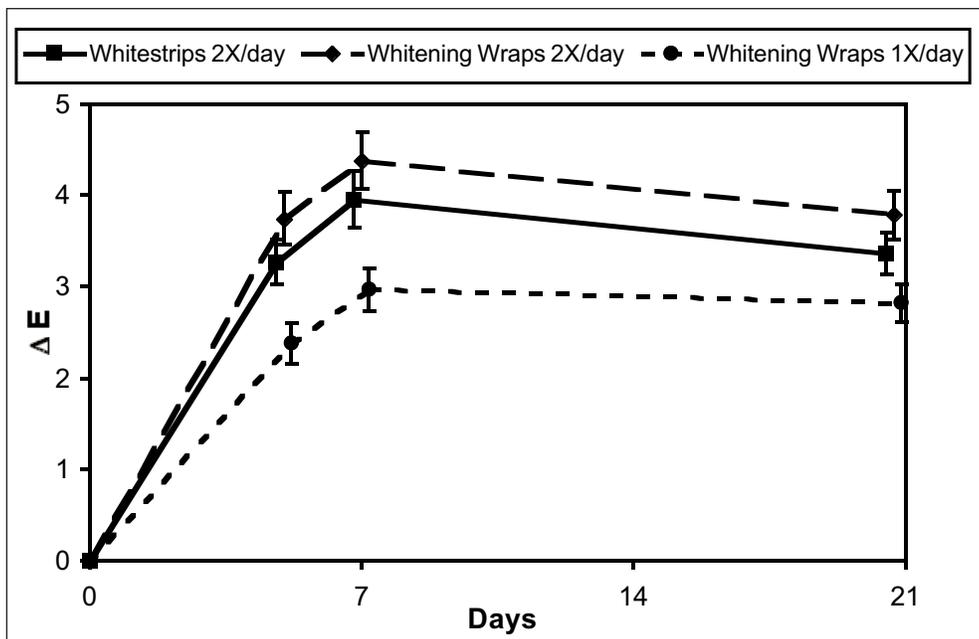


Figure 1. Mean change in E for all teeth at 5, 7 and 21 days.

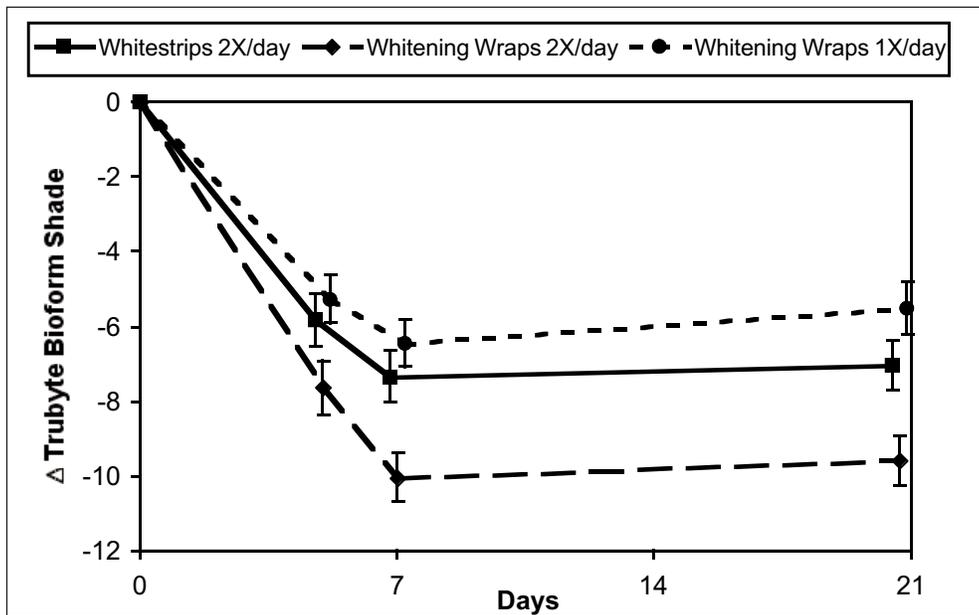


Figure 2. Mean change in Trybyte Bioform for all teeth at 5, 7 and 21 days.

Since the strip-based tooth whitening system was introduced on the market, numerous studies have been conducted to evaluate the effectiveness of the system. Unfortunately, there have been a variety of HP concentrations used in the strips and comparisons of study data are difficult. The first over-the-counter product introduced contained 5.3% HP and was to be used twice a day for 14 days (Gerlach, Barker & Sagel, 2002). Subsequently, another over-the-counter strip was introduced containing 6.0% HP, which was to be used twice a day for seven days (Gerlach, Gibb & Sagel, 2002). A "professional strength" strip containing 6.5% HP was introduced at the same time and was to be used twice a day for 21 days (Li & others, 2003). The latest over-the-counter product is 10% HP and is intended to be used twice a day for seven days. This "professional strength" product is now 14% HP (Gerlach & Sagel, 2004; Swift & others, 2004).

This study is an attempt to inform dental practitioners about the new products, their concentration and efficacy both during use and post-bleaching. It appears that there is minimal reversal in color when wraps and strips are used. Perhaps this is because the teeth's "inherent lightness potential" (Matis, 2003) is not exceeded, therefore, no color reversal occurs.

Both smokers and non-smokers purchase over-the-counter products. The authors are not aware of any data available in the scientific literature that identifies whether smokers bleach differently than non-smokers. The mean age of smokers was seven years younger than the mean age of non-smokers. Non-smokers were measured to be significantly different in L^* and a^* than smokers, but smokers were measured to be significantly different with the Trubyte Bioform Color Ordered Shade Guide than non-smokers. There is no explanation for this finding.

The Whitening Wraps with 8% HP have not yet been distributed by the Ranir Corporation. It is impossible for consumers to know the concentration of active agent in tooth whitening products sold over-the-counter. Manufacturers are not required to place concentrations on the labels, only the name of the active agent. The dental profession needs to encourage manufacturers to place the concentration of active agent on labels so that patients can make an informed decision as to what concentration of whitening gel is in the product they are purchasing.

CONCLUSIONS

All products had significant tooth whitening 14 days post-bleaching.

The subjects using WW2 were significantly lighter overall in tooth whitening than those using WP2 in L^* and shade guide values and improved, but not significantly so, in all other color measured parameters.

Subjects using WP2 were significantly lighter overall in tooth whitening than those using WW1 in a^* , b^* , E and shade guide values and improved, but not significantly so in all other color measured parameters.

There was no difference in tooth sensitivity, but WW1 and WP2 caused less gingival sensitivity than WW2.

The mean age of smokers was seven years younger than non-smokers who qualified.

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