Literature Review

Review of the Effectiveness of Various Tooth Whitening Systems

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Clinical Relevance

Tooth whitening is observable with all methods of bleaching. Dentist-prescribed overnight bleaching was shown to be the most effective method of bleaching.

SUMMARY

This review compares nine published studies conducted at the Indiana University School of Dentistry. Twenty-five products in four different systems were evaluated using the Trubyte Bioform Color Ordered Shade Guide and a Chroma Meter. The dentist-prescribed overnight bleaching delta mean shade guide value (DSGV) 10 weeks post-bleaching was 13.2 and delta E value (DEV) 4.7; dentist-prescribed daytime bleaching DSGV 10 weeks post-bleaching was

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10.5 and DEV 3.4; in-office bleaching DSGV 10 weeks post-bleaching was 6.7 and DEV was 2.1; over-the-counter bleaching DSGV two weeks post-bleaching was 7.2 and DEV was 4.1. A color difference of Delta E 2.6 is perceivable. Tooth whitening is observable with all methods of bleaching. Dentist-prescribed overnight bleaching was shown to be the most effective method of bleaching.

INTRODUCTION

"Doctor, I want a whiter, brighter smile. What kind of bleaching works best?" Today's dentist is acutely aware of the value of tooth bleaching to his or her practice and patients, but they want to provide treatment based on reliable evidence. The challenge for dentists is to determine the effectiveness of various tooth-whitening systems, while keeping patients' safety paramount. This has become more and more difficult, as manufacturers continue to provide new products that purport to be superior to others currently on the market. Numerous claims are made based on higher concentrations of an active agent, the addition of desensitizing agents, better

formulations or the use of lights or other innovations, although it is a well known fact that dental bleaching is primarily time- and concentration-dependent.¹

While many studies have been published detailing the effectiveness of various bleaching agents, there are only a few that have looked at both in-office and athome systems.²⁻³ It is also very difficult to make valid comparisons between research accomplished at different sites using diverse instruments and techniques. Most published studies use the Vitapan classical Shade Guide (Vita Zahnfabrik, Bad Sackingen, Germany) for subjective evaluation, but it has not been demonstrated that the shade tabs are actually linear in color measurement.⁴ The Trubyte Bioform Color Ordered Shade Guide is grouped according to the Munsell Color Notation (each tab identified by hue, chroma and value) and has a wider spectrum of shades, but this shade guide still cannot be interpreted as absolute. A new shade guide has recently been introduced with more equal color spaces and an extended tooth-whitening range.⁵ Several different color-measuring instruments are being used for objective evaluation, but their values cannot currently be compared. In addition, the skill of the evaluator and lighting variables are other factors that need to be addressed and are challenging to control.

The American Dental Association (ADA) has recently revised its criteria for the Seal of Acceptance program with dentist-prescribed at-home, in-office and overthe-counter products, certifying the safety and efficacy of those products to a certain measurable standard. Only one dentist-prescribed at-home product has been awarded the ADA Seal of Acceptance at this time. Even though the guidelines for ADA acceptance have recently been revised for the efficacy of products, the biological safety criteria have not been changed since they were established in 1994.

In an attempt to provide an evidence-base for the dental practitioner, the purpose of this review article is to compare the effectiveness of various methods of tooth whitening by evaluating articles where most of the objective and all of the subjective evaluations were conducted using the same instruments. All study protocols were approved by the IUPUI Institutional Review Board, Indianapolis, IN, USA, and informed consent statements were signed by the subjects in the nine referenced studies.

COMPARABLE STUDIES

All of the studies cited in this review of tooth whitening agents:

• used the Trubyte Bioform Color Ordered Shade guide (Style A, Dentsply/York Division, Dentsply International Inc, York, PA, USA) as the subjective color evaluation instrument.

- were evaluated by the same person (except for one¹¹) who has lectured to dental students on color and shade evaluation for more than 25 years.
- used the Chroma Meter CR 321 (Minolta Corporation, Ramsey, NJ, USA)¹² with the exception of two; one used the Chroma Meter CR 121,¹¹ and the other used the ShadeEye (Shofu Inc, Kyoto, Japan).¹³ Each subject was evaluated for color using the Chroma Meter and utilized a customized cone that was disinfected between uses, while those evaluated with ShadeEye had a disposable cone used for each evaluation.
- were carried out in an area that had color-corrected lighting and were not influenced by outside light.
- used subjects who were enrolled with the same Inclusion/Exclusion criteria (Table 1), except for the study using over-the-counter products.

 Smoking was not an exclusion factor in that study.

The data used in this review represent values from the time dental bleaching was discontinued, as it would not be appropriate to begin when the studies were initiated. The in-office products would be two weeks ahead in the reversal of color when compared with those products that have one or two weeks of bleaching before reversal of color would begin.

Some of the reported studies were carried out for a much longer period than other studies. The data for this comparison were carried out to only 10 weeks for those studies that go longer, so that products could be compared.

Due to space limitations, only E and shade guide values are presented in this review; however, L*, a* and b* values are available from the referenced articles. The ADA states in the guidelines for acceptance of tooth bleaching products that the E value specified must be due to higher L* and lower b* values. 68 E values are included in the current review, because they come closest to the ability of the human eye to perceive color.

Each study was accomplished for a specific research objective. Six studies in this meta analysis were splitmouth design studies, where different sides of the mouth used a different formula, different times or concentrations. This is the most effective way to conduct clinical research on products, because, if all teeth are vital, then the potential for whitening of the contralateral teeth will be similar. It has been reported that crossover has not influenced color changes, if trays are made carefully and excess gel is not dispensed into the trays at the time of testing. One of the split mouth

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Study #	Products	Concentration	N	Bleaching	Time of Bleach	Post-Bleaching	Length of Study
3	Opalescence	10% CP	20	2 Weeks	Overnight	10 Weeks	12 Weeks
	StarBrite	35% HP	20	2 Weeks	2-3 x 10 Minutes	10 Weeks	12 Weeks
11	Opalescence	10% CP	30	2 Weeks	Overnight	22 Weeks	24 Weeks
	Placebo	0% CP	30	2 Weeks	Overnight	22 Weeks	24 Weeks
13	Whitestrip Supreme	10% HP	25	1 Week	2 x 30 Minutes	2 Weeks	3 Weeks
	Ranir Wrap	8% HP	26	1 Week	2 x 30 Minutes	2 Weeks	3 Weeks
	Ranir Wrap	8% HP	25	1 Week	30 Minutes	2 Weeks	3 Weeks
14	Opalescence	10% CP	25	2 Weeks	Overnight	4 Weeks	6 Weeks
	Opalescence	15% CP	25	2 Weeks	Overnight	4 Weeks	6 Weeks
15	Opalescence	15% CP + PF	32	2 Weeks	Overnight	10 Weeks	12 Weeks
	Nite White	16% CP +ACP	32	2 Weeks	Overnight	10 Weeks	12 Weeks
16	Rembrandt Xtra	16% CP	27	2 Weeks	2 Hours	10 Weeks	12 Weeks
	Rembrandt Xtra	16% CP	27	2 Weeks	2 Hours	10 Weeks	12 Weeks
17	Opalescence	20% CP	24	2 Weeks	2 x 60 Minutes	10 Weeks	12 Weeks
	Day White	7.5% HP	24	2 Weeks	2 x 60 Minutes	10 Weeks	12 Weeks
18	StarBrite	35% HP	20	1 Hour	In chair	11 Weeks	11 Weeks
	Opalescence Xtra B	38% HP	20	1 Hour	In chair	11 Weeks	11 Weeks
19	Accelerated	40% HP	4	15 Minutes	In chair	6 Weeks	6 Weeks
	ArcBrite	30% HP	4	1 Hour	In chair	6 Weeks	6 Weeks
	BriteSmile	15% HP	4	1 Hour	In chair	6 Weeks	6 Weeks
	Illumine	15% HP	4	1 Hour	In chair	6 Weeks	6 Weeks
	Niveous	27% HP	4	45 Minutes	In chair	6 Weeks	6 Weeks
	One-Hour Smile	35% HP	4	45 Minutes	In chair	6 Weeks	6 Weeks
	PolaOffice	35% HP	4	36 Minutes	In chair	6 Weeks	6 Weeks
	Zoom!	25% HP	4	1 Hour	In chair	6 Weeks	6 Weeks

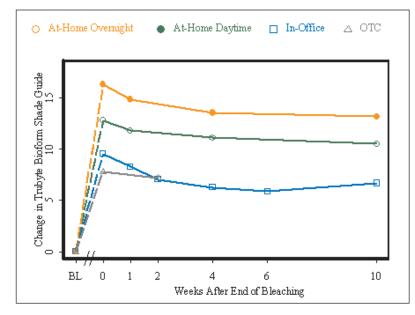


Figure 1. Mean delta shade of products evaluated at the Clinical Research Section of the Indiana University School of Dentistry. Baseline assessments were made two weeks before the end of bleaching for at-home night time and at-home daytime products one week before the end of bleaching for OTC products and approximately two hours before the end of bleaching for in-office products.

design studies compared the efficacy of a 10% CP vs a 15% CP.¹⁴ Another study compared the sensitivity reduction that occurs using a 15% CP product containing potassium nitrate and fluoride (PF) compared with another 15% CP product containing amorphous calcium phosphate (ACP).15 The objective of another study was to determine whether the use of reservoirs during daytime bleaching made a difference in the effectiveness of a product,16 while another study tested the null hypothesis that there was no difference between using the same equivalent concentrations of HP in agents containing HP and CP17 and the last split mouth study that compared the use of at-home vs in-office toothwhitening agents.3

Three studies in this meta analysis were not accomplished as split-mouth design studies, but on different cells of subjects. Included are two studies where the authors tested the null hypothesis that there are no differences between the effectiveness of different in-office products. The null hypothesis that there was no difference between the efficacy of using whitening strips compared with whitening

Table 2: Mean, 95% confidence interval for the mean, minimum, maximum and average percent loss of delta E and delta shade guide for each tooth whitening system.

	Group	Weeks	Mean	95% CI	Min	Max	%Loss
Delta E	At-home						
	Overnight	0	9.7	8.3 - 11.2	1.0	19.6	_
	•	1	6.7	5.2 - 8.2	1.4	18.6	31%
		4	4.9	3.5 - 6.4	0.4	15.9	49%
		10	4.7	3.0 - 6.5	1.6	13.4	51%
	At-home						
	Daytime	0	6.6	4.6 - 8.5	1.7	15.6	_
	,	1	4.6	2.6 - 6.6	0.8	14.2	30%
		4	3.4	1.5 - 5.4	0.8	6.8	48%
		10	3.4	1.4 - 5.4	1.2	12.6	48%
	In-office	0	5.4	3.2 - 7.5	1.2	11.1	_
		1	3.0	0.4 - 5.5	0.9	9.8	45%
		2	2.3	0.0 - 5.2	1.0	7.1	57%
		4	2.0	0.0 - 4.1	0.7	6.1	63%
		6	1.9	0.0 - 4.7	0.8	4.4	65%
		10	2.1	0.0 - 4.7	1.2	6.3	60%
	ОТС	0	4.6	1.8 - 7.3	0.8	7.3	_
		2	4.1	1.4 - 6.9	0.6	7.3	10%
Delta Shade	At-home						
	Overnight	0	16.3	15.1 - 17.5	2.0	25.0	_
	- · · · · · · · · · · · · · · · · · · ·	1	14.8	13.6 - 16.1	1.0	25.0	9%
		4	13.6	12.3 - 14.8	0.0	22.0	17%
		10	13.2	11.8 - 14.6	1.0	23.0	19%
	At-home						
	Daytime	0	12.8	11.1 - 14.5	5.3	20.0	_
	2 0,	1	11.8	10.1 - 13.5	4.7	19.7	8%
		4	11.1	9.4 - 12.8	4.3	18.3	13%
		10	10.5	8.9 - 12.2	4.0	17.7	18%
	In-office	0	9.6	7.6 - 11.5	-1.3	19.2	_
	011100	1	8.3	6.0 - 10.6	1.0	16.7	13%
		2	7.0	4.5 - 9.6	-1.3	14.0	26%
		4	6.3	4.3 - 8.2	-3.0	15.7	34%
		6 10	5.9 6.7	3.3 - 8.4 4.8 - 8.5	-3.0 -4.3	14.8 17.7	39% 30%
	OTC	0	7.8	5.7 - 9.9	0.0	16.0	_
	010	2	7.8 7.2	5.7 - 9.9 5.2 - 9.3	0.0	16.0	— 7%

wraps was tested in one study.¹³ The last of the nine studies was accomplished to determine the efficacy and clinical safety of 10% CP and was accomplished using a placebo vs 10% CP in separate subjects.¹¹

All peer-reviewed published studies that were accomplished at the Clinical Research Section at the Indiana University School of Dentistry are included in this meta analysis. Table 1 identifies the studies, products used, concentrations, number of subjects, bleaching times and post-bleaching follow-up evaluations. These studies had examinations at slightly different follow-up times, so the data are summarized at the end of bleaching, then at approximately 1, 2, 4, 6 and 10 weeks after completion of the bleaching. Because all data from the individual studies was available, this meta analysis was performed using an ANOVA. The

ANOVA included terms for week, tooth type and product, as well as interactions among the three factors and baseline measurements as covariates. Random effects for study, subject, subject-by-week and subject-by-tooth type were also included. Products were grouped together to identify means, along with 95% confidence intervals for the means, ranges and average % loss from the end of bleaching (Table 2).

Dental Prescribed Overnight Bleaching

There are four studies in which a total of six products were used overnight. $^{3,11,14\cdot15}$ Three of the studies used 10% CP. 3,11,14 and another study used 15% and 16% CP. 15

The mean delta of the shade guide values of the six products was 16.3 immediately after bleaching and 13.2 ten weeks post-bleaching (Table 2, Figure 1). The

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mean delta of the E value was 9.7 immediately after bleaching and 4.7 ten weeks post-bleaching (Table 2, Figure 2).

Dental Prescribed Daytime Bleaching

There are two studies in which four products were used during the day. 16-17 One study used 16% CP, which was used for two hours once a day 16 either with or without reservoirs. The other study used products containing 20% CP and 7.5% HP. The products in that study were used twice a day for one hour. 17

The mean delta of the shade guide values of the products was 12.8 immediately after bleaching and 10.5 ten weeks post bleaching (Table 2, Figure 1). The mean delta of the E value was 6.6 immediately after bleaching and 3.4 ten weeks post bleaching (Table 2, Figure 2).

In-office Bleaching

There were three studies in which 11 in-office products were used. 3.18-19 One study used 35% HP, which was placed three times for 10 minutes at two different sittings. The second study used 35% and 38% HP, which were placed three times for 20 minutes each at the same sitting. The third study used eight products containing anywhere from 15%-40% HP. The eight products were used for various periods of time (Table 1).

The mean delta of the shade guide values of the 11 products was 9.6 immediately after bleaching and 6.7 ten weeks post-bleaching (Table 2, Figure 1). The mean delta of the E value was 5.4 immediately after bleaching and 2.1 ten weeks post-bleaching (Table 2, Figure 2).

Over-the-counter Bleaching

There is one study in which products were used three different ways.¹³ One product contained 10% HP and was used for 30 minutes twice a day for one week. Both of the other agents contained 8% HP. One was used for 30 minutes once a day and the other for 30 minutes twice a day for one week.

The mean delta of the shade guide values of the three products was 7.8 immediately after bleaching and 7.2 two weeks post-bleaching (Table 2, Figure 1). The mean delta of the E value was 4.6 immediately after bleaching and 4.1 two weeks post-bleaching (Table 2, Figure 2).

DISCUSSION

All groups in the study had at least 20 subjects, with the exception of one study, where eight products were evaluated using 32 subjects. This was considered a pilot study. Six of the studies were half-mouth design studies. This study design is the most valid study design for tooth-whitening research. Each tooth in the half-mouth responds to the agent that covers it. With well-

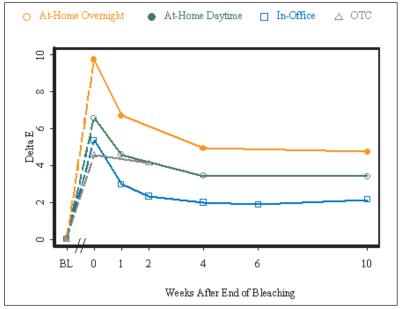


Figure 2. Mean delta E of products evaluated at the Clinical Research Section of the Indiana University School of Dentistry. Baseline assessments were made two weeks before the end of bleaching for at-home night time and at-home daytime products one week before the end of bleaching for OTC products and approximately two hours before the end of bleaching for in-office products.

made reservoirs, it has been determined that crossover effects, if there were any, are negligible.¹⁴

Manufacturer's recommendations were followed. Where reservoirs were recommended, they were placed. In the study of eight in-office products, ¹⁹ invitations to observe the procedures were extended to all of the manufacturers whose products were used in the study. Four of the eight manufacturers sent representatives to help ensure their products were used according to their instructions.

A study by Auschill and others evaluated the time it took for tooth whitening agents from different systems to reach six Vita shade guide tab changes.² These authors determined that it took 31.85 cycles of 30 minutes using an over-the-counter product, 7.15 cycles of using an at-home product overnight and 3.15 cycles of using an in-office product to reach the shade tab change desired.

The research center at Loma Linda University School of Dentistry, Loma Linda, CA, USA, routinely uses a colorimeter and Vitapan classical Shade Guide (Vita Zahnfabrik) to measure changes in color. In their study evaluating the effectiveness of three tooth-whitening systems, Li and others reported that the overnight system was the most effective of the three systems in a 21-day study.²⁰

Neither of the studies that looked at three different systems carried out their evaluation periods past the endpoint of bleaching. It is important to look at color reversal for at least four weeks after completion of the bleaching, so that the true endpoint can be identified, instead of a false endpoint that does not indicate what color patients can expect their teeth to remain for an extended period of time.

There are only two *in vivo* studies that have determined the perceptibility of color using a colorimeter. 21-22 In one study, 21 it was found that a mean color of 3.7 Delta E units between composite veneers and sound teeth was rated as a perfect match in the oral environment. In the other *in vivo* study, 22 it was found that 50% of the observers could perceive a color difference of 2.6 Delta E units with interchangeable right and left denture teeth in a denture base.

The current study compared products used for a certain time period. Bleaching is time- and concentration-dependent. The current study documents the relative lightening that has been shown to occur where research has been conducted with various systems according to manufacturers' recommendations.

CONCLUSIONS

Tooth whitening is most effective when bleaching gel is placed in trays and the trays are used overnight. The second most effective system is placing the tooth whitening gel in a tray and using it during the daytime for shorter periods of time.

In-office tooth whitening systems cause the teeth to become light immediately after bleaching. However, two weeks after completing the bleaching treatment, over-the-counter tooth whitening was as effective as in-office tooth whitening. For this reason, most in-office systems recommend tray bleaching as a follow-up procedure to ensure long-term effectiveness.

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