

2670. Safety and Efficacy Results of Whole Mouth Tooth Whitening Treatments

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Introduction

At-home whitening has become one of the most popular procedures in esthetic dentistry due to its convenience, tooth whitening efficacy, and decreased cost compared with in-office whitening treatments¹. A variety of products are available for at-home tooth whitening, ranging from heat moldable trays and brush-on tooth whiteners, to tooth whitening pens and whitening strips. In this study, an experimental tooth whitening system (ETWS) using a soft, flexible arch conforming tray was pre-dosed with a 10% w/w hydrogen peroxide bleaching gel and tested against two commercially available whitening products.

Objectives

- To evaluate the tooth whitening efficacy on the maxillary and mandibular arch of a 10% w/w experimental hydrogen peroxide gel pre-dosed in a flexible tray compared with two commercially available tooth whitening strip products after 7 days of product use.
- To evaluate the safety of ETWS compared with two commercially available tooth whitening strip products after 7 days of product use.

Methods

Clinical procedure

In this parallel and examiner-blind study, a total of 114 subjects were randomized to one of three treatments:

- experimental tooth whitening system (ETWS), 10% w/w hydrogen peroxide
- Crest Whitestrips Classic (CWSC) 6% w/w hydrogen peroxide
- Crest Whitestrips Premium (CWSP) 10% w/w hydrogen peroxide.

Inclusion criteria included vital teeth with two of the four mandibular and maxillary incisors having a VITA shade score of A2 or greater. Subjects started their randomized treatment on the mandibular teeth for 7 days, after which they began to use the same treatment on their maxillary teeth for 7 days. The ETWS was worn for 45 minutes once daily. The Crest products were applied according to the manufacturer's instructions, which was twice-daily wear for 30 minutes each application. Subjects brushed twice daily for 1 minute with a standard toothpaste. Compliance, efficacy, and safety were assessed after 5 and 7 days of treatment. The efficacy parameters employed were based on the VITA Shade Guide scores measured on the mandibular and maxillary incisors of each subject at each examination. Subjects were also asked to complete a questionnaire regarding tooth whitening after 3 days of treatment.

Statistical methods

For each of the Day 5 and Day 7 visits, an analysis of covariance model was used to investigate the mean change from baseline in VITA Shade Guide rank score. VITA Shade Guide scores were transformed to rank scores based on information provided by the manufacturer (in which higher scores represent darker shades). This model included the factor treatment group, and employed baseline mean VITA Shade Guide rank score, age, and smoking status as covariates. For each pair of treatment groups, a 95% confidence interval for the difference between the (covariable-adjusted) means for the two treatments was constructed. Within-treatment product effects were assessed by analyzing the mean changes from baseline using paired *t*-tests. All statistical tests of hypotheses were two-sided and employed a significance level of $\alpha = 0.05$.

Results

- After 5 days and 7 days of treatment, ETWS, CWSC, and CWSP produced statistically significant whole mouth tooth whitening compared with baseline.
 - After 5 days, reductions in VITA shades were 2.51, 2.45, and 1.91 for ETWS, CWSP, and CWSC, respectively.
 - After 7 days, reductions in VITA shades were 3.62, 3.32, and 3.11 for ETWS, CWSP, and CWSC, respectively.
- **Figure 1** and **Table 1** provide a summary of VITA shade reductions and treatment differences.

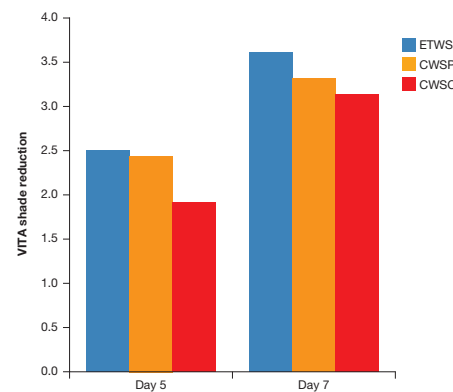


Figure 1. Summary of VITA shade reductions. CWSC, Crest Whitestrips Classic; CWSP, Crest Whitestrips Premium; ETWS, experimental tooth whitening system.

Table 1. Summary of Treatment Comparisons

Visit	Comparison	Difference	p value*	95% CI
Day 5	ETWS/CWSC	0.06	0.8581	(-0.62, 0.75)
	ETWS/CWSP	0.58	0.0955	(-0.10, 1.27)
	CWSC/CWSP	-0.52	0.1268	(-1.20, 0.15)
Day 7	ETWS/CWSC	0.30	0.3879	(-0.38, 0.98)
	ETWS/CWSP	0.51	0.1478	(-0.18, 1.20)
	CWSC/CWSP	-0.21	0.5360	(-0.88, 0.46)

ANCOVA, analysis of covariance; CI, confidence interval; CWSC, Crest Whitestrips Classic; CWSP, Crest Whitestrips Premium; ETWS, experimental tooth whitening system.
*p value from post-ANCOVA pair-wise comparisons, adjusted for the baseline VITA Shade Guide rank scores, age, and smoking status.

- Subjects were asked on Day 3 whether their teeth were whiter than they were at the start of treatment.
 - The response for mandibular whitening was 51.4% for ETWS, 36.8% for CWSC, and 53.7% for CWSP.
 - The response to maxillary whitening was 70.6% for ETWS, 70.7% for CWSP, and 54.1% for CWSC.
- The total number of adverse events (AEs) was similar for both of the two higher peroxide concentrations. The types of comments are similar to those reported in the literature². All oral AEs were transient in nature and resolved after cessation of treatment.

Conclusions

- All three products tested produced statistically significant whole mouth tooth whitening compared with baseline after 5 days and 7 days of treatment.
- There was no difference in the whitening produced for ETWS, once daily for 45 minutes, versus CWSP, twice daily for 30 minutes.
- The majority of subjects in the ETWS group and the CWSP group observed whitening after a 3-day period.
- The AE profile for ETWS was similar to both Crest Whitestrips products.

References

1. Li Y. 2003. The safety of peroxide-containing at-home tooth whiteners. *Compend Contin Educ Dent* 24:384-9.
2. Bordas A, Bosma ML, Kleber CJ et al. Oral tolerability of hydrogen peroxide whitening gel formulations. Presented at the 85th International Association for Dental Research Congress, 21-24 March 2007. New Orleans, LA, USA. Abstract 2821.

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