

ABSTRACT

Oral cavity and systemic exposure to peroxide are important measures of tooth whitening safety. Gerlach et al. have demonstrated the comparative tooth bleaching efficacy of Crest Whitestrips™ (CWS), 10% and 20% carbamide peroxide (CP) Opalescence tray products (*Comp Contin Educ Dent* 21, Suppl. 29, 2000). This clinical trial evaluated the device, tooth and salivary hydrogen peroxide (HP) levels during use of two tray systems and CWS. This was a single center, randomized, cross-over design study with 12 subjects; only maxillary teeth were treated. For CWS, the sampling times were 5, 10, 30 & 60 min.; tray product sampling times were 10, 30, 60 & 120 min. CWS started with 5.3% HP, decreasing to 2.6% HP (30 min.) and 2.2% HP (60 min.). CWS HP level on the tooth was 2.3% (5 min.), 1.7% (30 min.) and 1.2% (60 min.). The 10% CP tray with 3.4% HP decreased to 2.6% HP (120 min.). The 20% CP tray with 6.7% HP decreased to 3.7% HP (120 min.). For the 10% tray, the tooth HP levels were 1.8% HP (10 min.) and 1.6% HP (120 min.). For the 20% tray, the tooth HP levels were 2.9% HP (10 min.) and 1.9% HP (120 min.). Median salivary HP levels were not above 0.013% HP at any sampling time for any product. Daily HP exposure (twice the area under the curve) was significantly lower for CWS than daily exposure to the 10% or 20% CP tray products ($p < 0.10$). **This clinical research confirms the safety of CWS by demonstrating the minimal systemic exposure and rapid degradation of HP during CWS use.**

INTRODUCTION

Tooth whitening using carbamide or hydrogen peroxide in a dentist-fabricated tray is a very effective and popular dental procedure. Treatment is commonly done at home (during the day or overnight) over a period of several weeks. An important measure of safety is the oral cavity exposure to peroxide during the course of tooth whitening. This study compared the peroxide degradation rates (in the device, on teeth and in saliva) and area under the time-concentration curves (AUC) after use of 3 marketed tooth whitening systems.

MATERIALS AND METHODS

Products tested:

- Crest Whitestrips [a polyethylene film with a peroxide gel (pH ~ 5.8, 5.3% HP)]
- 10% Opalescence Professional Tooth Whitening Kit (10% CP, 3.3% HP)
- 20% Opalescence Professional Tooth Whitening Kit (20% CP, 6.7% HP)

Study Design

This was a supervised cross-over study. HP levels were measured in the device, on the teeth, and in saliva. Each subject completed a single dosing-time point/day, four time points/test product, for a total of 12 study days. For CWS, the sampling times were 5, 10, 30 & 60 min.; tray product sampling times were 10, 30, 60 & 120 min. (CWS are worn for 30 min., twice a day. Opalescence products can be worn for 2-8 hours (overnight) depending on professional recommendation.) Prior to dosing, subjects brushed with Crest Cavity Protection.

Sample Analyses

At the randomized sample time, a saliva sample was collected. The device was then removed and the entire CWS or a gel sample from the Opalescence tray was placed in a beaker. Some of the residual gel was scraped from the anterior maxillary teeth. Acid was added immediately to each sample. The strip sample for CWS, and the gel from the tray scraping for Opalescence were analyzed using an indirect iodometric titration. The teeth scraping and the saliva sample were both analyzed using a PeroXOquant Quantitative Peroxide Assay (Pierce), which is an indirect colorimetric analysis.

RESULTS

Figure 1. HP in Devices

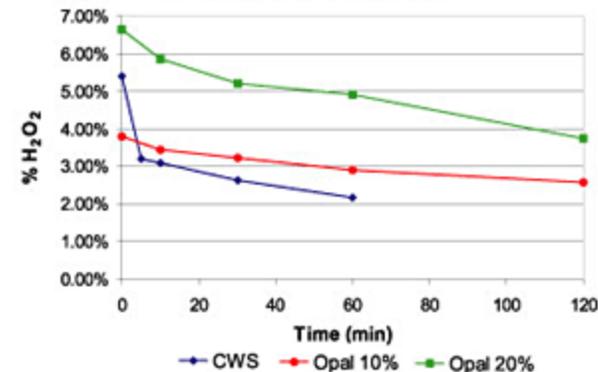


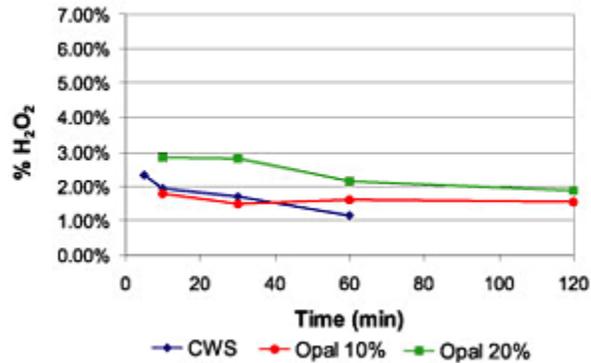
Table 1. Overall Daily HP Exposure from the Device used for the Recommended Exposure Time*

	Mean Area Under the Curve (AUC)
Crest Whitestrips (2 X AUC from 0-30 min.)	193.14 ± 31.03**
10% Opalescence (AUC from 0-120 min.)	361.76 ± 27.66
20% Opalescence (AUC from 0-120 min.)	592.71 ± 53.98

* CWS are worn for 30 minutes, twice a day (deliver ~ 22 mg HP/day). Opalescence can be worn for 2-8 hours (delivers ~ 20 - 30 mg HP/day for 10% Opal. and 40 - 60 mg HP/day for 20% Opal.).
 ** Significantly different ($p < 0.10$) using the non-parametric signed-rank test.

Daily HP exposure (based on AUC) for HP in devices was significantly lower for CWS than daily exposure to the 10% or 20% tray products ($p < 0.10$).

Figure 2. Residual HP on Teeth



CONCLUSION

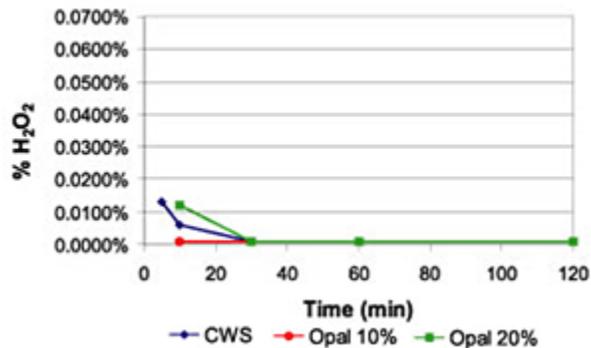
-Daily HP exposure for HP in devices was significantly lower for CWS (2X AUC at 30 min.) than for the 10% or 20% CP tray products (AUC at 120 min.).

-Despite the differences in daily exposure (as measured by AUC), the very low salivary HP levels from all three marketed products indicate their low potential to allow systemic exposure to HP.

-This clinical research confirms the safety of CWS by demonstrating the minimal systemic exposure and rapid degradation of HP during CWS use.

HP levels in the tooth whitening gel delivery devices and on teeth decreased over wear time for all products.

Figure 3. HP in Saliva



Median salivary HP levels were not above 0.013% HP at any sampling time for any product.