

Safety of Vital Tooth Bleaching with 6% Hydrogen Peroxide Whitening Strips: Evidence from 18 Clinical Trials

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ABSTRACT

Objective: This research summarizes an extensive clinical trials database on 6% hydrogen peroxide strip-based tooth whitening system in order to ascertain factors that contribute to clinical safety and tolerability. **Methods:** Data from 18 different randomized clinical trials were included in the meta-analysis. This inclusive assessment involved study subjects who used flexible polyethylene, whitening strips coated with a 6% hydrogen peroxide bleaching gel. Treatment was twice daily for 30 minutes over a 2-week period. Safety and tolerability were assessed from clinical examination and interview. A logistic regression model was used to identify possible risk factors for tooth sensitivity and oral irritation. **Results:** The analysis included 316 subjects (18-82 years of age) with complete safety data. Mild and transient tooth sensitivity (18.0%) and oral irritation (17.1%) represented the most common adverse events during treatment. Age was a significant ($p = 0.0008$) effect in the tooth sensitivity model, with older subjects reporting less tooth pain during treatment. Race and gender were not significant contributors. Other adverse events were unremarkable, and most resolved during the period of active treatment. Over 97% of adverse events were considered to be “mild” in severity, and only 2 subjects (0.6% of the population) discontinued treatment early due to an adverse event. **Conclusion:** This meta-analysis further establishes the clinical safety and tolerability of vital bleaching with 6% hydrogen peroxide whitening strips.

OBJECTIVE

This research summarizes an extensive clinical trials database on 6% hydrogen peroxide strip-based tooth whitening system in order to ascertain factors that contribute to clinical safety and tolerability.

MATERIALS AND METHODS

The 6% hydrogen peroxide polyethylene strip-based tooth whitening system (marketed as Crest® Whitestrips®) clinical database was used for this assessment. Eighteen studies (316 clinical subjects) were identified in which subjects used the 6% hydrogen peroxide strips (9-12 mg hydrogen peroxide depending on the arch) for 30 minutes, twice a day for a 2-week period.

Demographic and Behavior Parameters

Sample Size	316
Age	18-82 (36)
Gender (Female)	229 (72%)
Ethnicity:	
White	246 (77.9%)
Hispanic	27 (8.5%)
Black	24 (7.6)
Tobacco Use	34 (11%)
Coffee/Tea Use	274 (87%)

Safety Evaluations

Dental Hypersensitivity and Oral Irritation Assessment:

The assessment was conducted via questioning of subjects at each visit about the presence or absence of hypersensitivity and irritation through an oral status interview.

Statistical methodology:

The potential risk factors for tooth sensitivity and oral soft tissue irritation were identified using a logistic regression model.

RESULTS

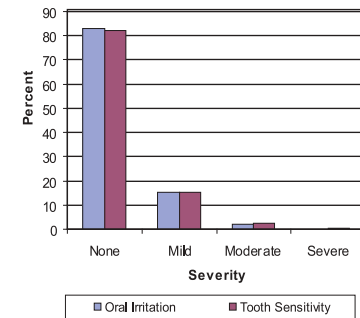
The most common adverse events (AEs) in the 18 clinical trials were:

- Tooth sensitivity, reported by 18.0% of clinical subjects
- Oral irritation, reported by 17.1% of subjects

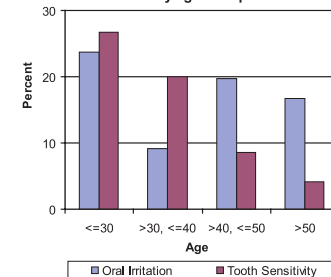
Adverse Events By Severity

- >97% of adverse events were of mild severity.
- Most adverse events resolved during the period of active treatment or within 1-2 days after treatment was completed.
- Only 2 subjects (0.06%) stopped treatment because of an adverse event.

Reported Adverse Events
By Severity



Reported Adverse Events
By Age Group



Adverse Events by Risk Factor

- Only age was identified as a factor that was statistically significantly associated with tooth sensitivity ($p = 0.0008$).
- A smaller percent of older clinical subjects reported tooth sensitivity than younger subjects.

CONCLUSION

- ❖ This meta-analysis further establishes the clinical safety and tolerability of vital bleaching with 6% hydrogen peroxide whitening strips (Crest Whitestrips).
- ❖ Mild, transient tooth sensitivity (18.0%) and oral irritation (17.1%) were the most commonly reported adverse events with 6% hydrogen peroxide strips.