

**Clinical Study to Examine Orthodontic Stain Removal by BriteSmile In
Office Tooth Whitening System**

Protocol # LL-BWT-0700-ORT

Interim Report

Sponsored by:

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Objective.

The objective of this study was to investigate the efficacy of the currently marketed BriteSmile Tooth whitening system upon removal of dental stains induced as a result of orthodontic therapy and to investigate the kinetics of removal of orthodontic stain.

Introduction.

The appearance of human dentition can be improved by both conservative and non conservative approaches. The conservative approaches include orthodontics and tooth bleaching because these methods generally do not require removal of sound tooth structures or acceptably shaped or spaced dentition.

Orthodontic therapy sometimes results in iatrogenic brown or white tooth discoloration which is due to a number of factors including:

1. Chronic stasis of dental plaque because bonded brackets tend to accumulate food debris and dental plaque. The result of this accumulation is localized regions of white demineralized lesions.
2. Orthodontic cements penetrate the tooth structure and produce localized regions of brown discoloration.
3. Release of metals orthodontic brackets may cause the release of iron which results in a red-brownish discoloration.

Tooth stains arising as a result of orthodontic treatment sometimes does not fulfill the total esthetic needs of the patients (and their parents). To overcome this disadvantage, enamel microabrasion or tooth whitening are sometimes indicated after orthodontic therapy.

The purpose of the proposed study was to investigate the safety and efficacy of the BriteSmile Tooth whitening system upon removal of iatrogenic orthodontic induced dental stain and understand the orthodontic stain removal process. Seventy five subjects in the age range of 16-18 with iatrogenic orthodontic induced dental stain were selected to participate in this study. One group of subjects received the BriteSmile treatment for 20 minutes, the second group received the treatment for 40 minutes and the final group received the treatment for 60 minutes.

Pre and post treatment tooth color was measured using both the subjective and the objective methods. The subjective methods consisted of the shade guide and the objective method of measuring tooth stain involved the use of the Chroma meter which measures color in the L* a* b* color space.

Methods

Study Design

Seventy five (75) subjects between the ages of 16-18 who have had orthodontic therapy and have stained dentition were selected to participate in this parallel, three cell clinical trial. The first group of twenty five subjects were treated with the BriteSmile System for 20 minutes. The second group of twenty five subjects were treated for 40 minutes (two twenty minute periods) and the third group was treated for one hour (three twenty minute periods).

Subjects

Based on the inclusion/exclusion characteristics described below, seventy five (75) subjects were selected to participate in this study.

Inclusion Characteristics

1. Parent or guardian signed an informed consent form.
2. Good general health as evidenced by the medical history.
3. Ages 16 to 18 (male or female).
4. Availability for the 6 month duration of the study.
5. Have not undergone a professional whitening treatment.
6. Have stained dentition as a result of orthodontic therapy.

Exclusion Characteristics

1. Presence of orthodontic appliances.
2. A soft or hard tissue tumor of the oral cavity.
3. Carious lesions requiring immediate treatment.
4. Restorations on all anterior teeth which will interfere with color measurement procedures.
5. Advanced periodontal disease (characterized by the presence of purulent exudate, tooth mobility and/or extensive alveolar bone loss).
6. Is participating in another clinical study or panel test.
7. Pregnant women or women who are breast feeding.
8. Congenital tooth stains or dental defects.

4. Tooth whitening procedure

a. 20 Minute Treatment

1. Supervise tooth brushing the subject for 30 seconds.
2. Take 35 mm photographs, measure color, GI, PI and perform clinical soft and hard tissue examinations.
3. Apply isolation materials to the maxillary and mandibular gingiva and extend approximately 1 mm onto the tooth surfaces.
4. Insert cheek retractor and cotton rolls in the vestibules.
5. Insert bite block or fiber-optic positioner.
6. Apply Vaseline Petroleum Jelly to the lips.
7. Apply whitening gel approx. 2 mm thick to the teeth using a bend-a-brush.
8. Turn on light and place it in contact with the fiber-optic positioner.
9. Expose teeth to the light and whitening gel for 20 minutes.
10. Turn off light
11. Remove light, isolation materials and clean teeth with an air water syringe.
12. Supervise tooth brushing the subject for 30 seconds.
13. Take 35 mm photographs, measure color, GI, PI and perform clinical soft and hard tissue examinations.

b. 40 Minute Treatment

1. Supervise tooth brushing the subject for 30 seconds.
2. Take 35 mm photographs, measure color, GI, PI and perform clinical soft and hard tissue examinations.
3. Apply isolation materials to the maxillary and mandibular gingiva and extend approximately 1 mm onto the tooth surfaces.
4. Insert cheek retractor and cotton rolls in the vestibules.
5. Insert bite block or fiber-optic positioner.
6. Apply Vaseline Petroleum Jelly to the lips.
7. Apply whitening gel approx. 2 mm thick to the teeth using a bend-a-brush.
8. Turn on light and place it in contact with the fiber-optic positioner.
9. Expose teeth to the light and whitening gel for 20 minutes.
10. Remove light.
11. Suction off whitening gel.
12. Apply fresh layer of whitening gel approx. 2 mm thick to the teeth using a bend-a-brush.
13. Place light in contact with the fiber-optic positioner.
14. Expose teeth to the light and whitening gel for 20 minutes.
15. Remove light, isolation materials and clean teeth with an air water syringe.
16. Supervise tooth brushing the subject for 30 seconds.
17. Take 35 mm photographs, measure color, GI, PI and perform clinical soft and hard tissue examinations.

c. 60 Minute Treatment

1. Supervise tooth brushing the subject for 30 seconds.
2. Take 35 mm photographs, measure color, GI, PI and perform clinical soft and hard tissue examinations.
3. Apply isolation materials to the maxillary and mandibular gingiva and extend approximately 1 mm onto the tooth surfaces.
4. Insert cheek retractor and cotton rolls in the vestibules.
5. Insert bite block or fiber-optic positioner.
6. Apply Vaseline Petroleum Jelly to the lips.
7. Apply whitening gel approx. 2 mm thick to the teeth using a bend-a-brush.
8. Turn on light and place it in contact with the fiber-optic positioner.
9. Expose teeth to the light and whitening gel for 20 minutes.
10. Remove light.
11. Suction off whitening gel.
12. Apply fresh layer of whitening gel approx. 2 mm thick to the teeth using a bend-a-brush.
13. Place light in contact with the fiber-optic positioner.
14. Expose teeth to the light and whitening gel for 20 minutes.
15. Repeat steps 10-14
16. Remove light, isolation materials and clean teeth with an air water syringe.
17. Supervise tooth brushing the subject for 30 seconds.
18. Take 35 mm photographs, measure color, GI, PI and perform clinical soft and hard tissue examinations.

Tooth Color Measurement Procedures

Tooth color was measured using both the subjective and objective methods. Subjective color measurements were obtained using the Vita Shade Guide. These procedures were carried out under standard color corrected operatory light by the same investigators to avoid inter investigator variability. Shade changes were measured by obtaining the shade of teeth numbers 7, 8, 9 and 10 under color corrected operatory light. The shade of each tooth was scored by arranging the Vita guide according to the degree brightness as shown below and recommended by the manufacturer and counting the number of tabs. The overall change in shade was then obtained by averaging the scores.

B1 A1 B2 D2 A2 C1 C2 D4 A3 D3 B3 A3.5 B4 C3 A4 C4
16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1

The objective change in tooth color was determined by averaging the color parameters for each tooth (i.e., #7, 8, 9 and 10) and color differences were calculated between the initial measurements and those measurements obtained post-treatment, three month recall and six month recall. This method has been

shown to be related to human color perception and recommended by the American Dental Association for determination of color differences between various tooth shades. In this method, the colors of teeth are compared using the CIELAB or the tristimulus color difference equation:

$$\Delta E = \{(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2\}^{1/2}$$

Where ΔE is the difference in color, the more positive the value the whiter the color. ΔL^* is the change in lightness, the greater the ΔL^* the whiter the teeth. Δa^* and Δb^* are chromacity values i.e. the amount of redness and the amount of yellowness.

Product Safety

Product safety was examined by clinical examinations and panelist questionnaires. The following tissues were examined before and after treatment.

1. Soft Palate
2. Hard Palate
3. Gingival Mucosa
4. Buccal and labial Mucosa
5. Mucogingival Folds
6. Tongue
7. Sublingual and submandibular areas
8. Salivary Glands
9. Tonsillar and pharyngeal areas

The panelist questionnaires consisted of the following questions:

Did you feel any discomfort during the procedure?

Not at all Slightly Moderately Greatly

If yes, please
explain_____

Did your teeth feel sensitive before the procedure?

Not at all Slightly Moderately Greatly

Did your teeth feel sensitive after the procedure?

Not at all Slightly Moderately Greatly

RESULTS

All seventy five subjects completed the first phase of the treatment. The age ranges were from 14 to 22. 25 subjects selected at random received one 20 minute treatment, 25 received two 20 minute treatments and 25 received three 20 minute treatments.

The three and six month recall are in progress and the following are the general observations immediately after treatment.

Safety Evaluation

Clinical examinations of the tissues of the oral cavity did not show any adverse effects related to the treatment. None of the subjects tested have complained of lasting pain or sensitivity. However, one subject stated she felt discomfort during the procedure and another felt transient discomfort immediately following the procedure which disappeared before she left the clinic.

Shade guide evaluation.

The evaluation of tooth shade using the vita guide was difficult in this group of subjects for the following reasons:

1. Orthodontic stains may be localized or generalized,
2. The stains often do not match the tabs on the guide,
3. The extent i.e., area of the stain is variable, and;
4. The discoloration is variable e.g., white spots around brackets and brown stain under the brackets.

As a result of the problems indicated above, general observations were made concerning the removal of stain and the time required to remove a particular type of stain. The observations are as follows:

General Observations

1. Resin tags from the composite used to attach orthodontic brackets must be removed before the whitening procedure. Notably, orthodontists do not normally remove resin tags which minimally penetrate the tooth surface. Preliminary results showed that the resin tags block the whitening action. Hence, it is desirable to remove the tags. The presence of the tags is difficult to detect visually but can be seen as a grayish scratch when a dental explorer is dragged across the tooth surface. We recommend that this be done routinely with all patients since the tags can persist for an undetermined length of time.

2. As indicated above, pain or discomfort does not appear to pose a problem with this age group.

Treatment Observations

20 Minute Exposure

Good for subjects with lighter natural tooth shade (i.e., A1 or B1) and considerable decalcification, however, if teeth have a yellow shade such as A3 or B3, the white lesions become more obvious.

40 Minute Exposure

Eliminates brown stain. Basically, the same as 20 minutes for teeth with lighter shades (A1, B1). However, does not adequately remove yellowness to obtain good result and, since white lesions become more opaque, the contrast of the white lesions and the natural yellow shade becomes more apparent.

60 Minute Exposure

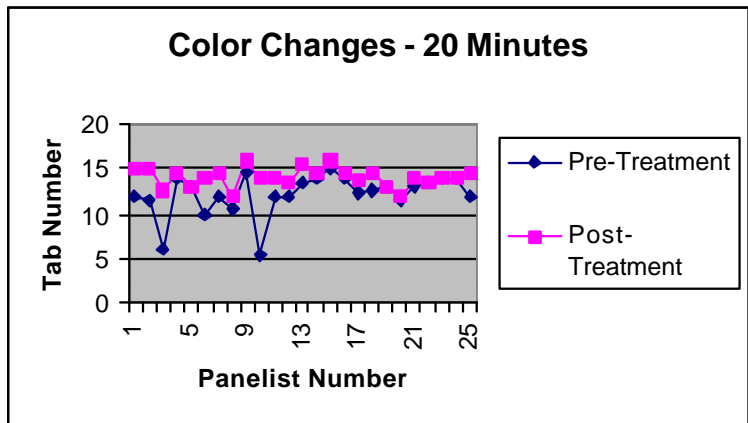
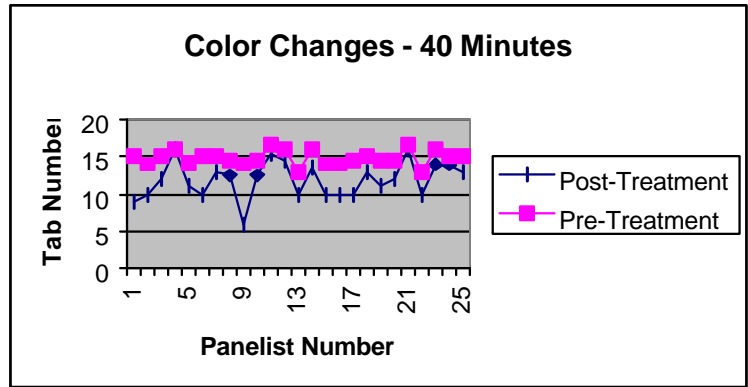
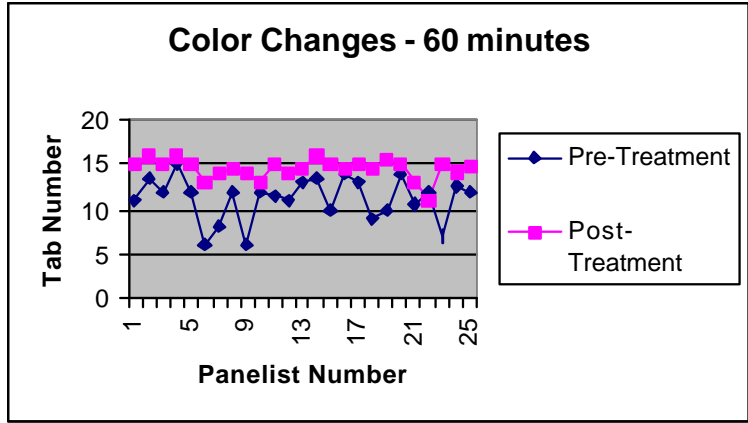
White lesions often become chalky or frosty in appearance. However, since yellow is removed, the contrast between the white lesions and natural tooth color is reduced. One hour exposure is best for teeth with natural yellow shades such as A3 or B3.

Thus, it would appear that 40 minutes is best for the lighter natural shades and 60 minutes for the natural yellow shades.

The measurement of the overall shade changes was also compounded by the fact that young individuals generally have whiter teeth when compared to older populations i.e., the baseline shades are normally in the lighter ranges e.g., the mean approximate starting shades for the three groups was calculated to be between C1 and A2; the score as detailed in methods being between 11 and 12. The maximum lightness score on the Vita guide is 16. Hence, with the use of the Vita guide the maximum improvement would be 5 (16 minus 11).

In treating subjects with localized discolorations the therapy is considered successful if the discolorations can be removed and teeth return to their natural measurable lightness i.e., B1 – A1 on the Vita Guide. The results of this study showed a majority of subjects returned to the B1 – A1 region after the whitening procedure.

The graphs below show the color improvement for each group of subjects.



The graphs above show that a majority of the subjects in the 60 and 40 minute treatment groups are in the shade range of B1 – A1

Chroma-meter Evaluations

The chroma meter measurements showed improvement in whiteness of all three groups. The results are tabulated below:

<u>Treatment Period</u>	<u>DE (SD)</u>
60 minutes	4.95 (2.40)
40 minutes	4.08 (2.26)
20 minutes	2.86 (1.45)

Statistical analysis by the F-test showed significant differences between the 60 minute treatment period and the 20 minute treatment period ($p < 0.05$). Similar significant differences were calculated between the 40 minute and the twenty minute treatment periods. Differences were not significant between the 40 and the sixty minute periods.

Conclusions

1. Safety

Product safety is not of significant concern within this group.

2. Efficacy

It is difficult to measure actual shade changes within this group of subjects due to the reasons discussed above. The data however indicates that orthodontic stain can be satisfactorily removed by the BriteSmile procedure and the treatment is considered to be successful because most of the subjects in the 60 and 40 minute treatment groups end up in the B1 – A1 shade range.

The efficacy is confirmed by the chroma-meter results.