

CLINICAL INVESTIGATION OF BRITESMILE TO GO PRODUCT

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Abstract

A clinical trial was conducted with 44 subjects to study and evaluate the safety and efficacy of the BriteSmile To Go (“BTG”) Pen, a teeth whitening system for vital tooth bleaching using a 5.25% hydrogen peroxide gel delivered from a brush-on pen. The investigation divided the subjects into two groups A and B. There were 22 subjects in each group. Group A received BTG for use at home and were given instructions to apply it twice daily for twelve days. Group B received application of BTG twice daily for a period of twelve days under the supervision of a dental professional at the La Jolla BriteSmile Center. This study demonstrated that BTG Pen achieved an average whitening improvement of approximately 4 shades as measured on the Vita Shade Guide. No sensitivity or any other complications were noted in any of the subjects.

Background

Over the past 10 years, there has been tremendous public demand for esthetic dentistry, fueled in part by the “Baby Boomer” generation, as well as a general increase in the public awareness of the products available for and targeted to the image conscious. BriteSmile is an industry leader in the development and advancement of safe and effective tooth whitening products for the dental profession and has introduced a simple and effective tool for the whitening of teeth. The objective of this study was to determine the clinical safety and effectiveness of the BTG whitening pen, as well as patient compliance due to its ease of use. Another objective was to evaluate the level of tooth sensitivity experienced by the test subjects, in order to compare to sensitivity levels observed in other methods, such as tray-administered tooth whitening.

Treatment Methodology

This study followed the International Standard Guidelines (ISO) for clinical investigation on human subjects. The ISO guidelines are intended to assist sponsors, monitors, investigators, ethics committees, regulatory authorities and bodies involved in the conformity of assessment of medical devices and to help evaluate the clinical investigation so the scientific validity of the results can be reproduced. The point of enrollment for each subject was the time at which, following recruitment, a subject voluntarily signed the informed consent. The dental and medical history of the subjects were evaluated and a random population was chosen with the majority having an average of A-3 shade or darker as measured on the Vita Pan Shade Guide. Following the BriteSmile medical evaluation guidelines, pregnant or nursing women, those with severe or moderate periodontal disease, and any other medical or dental complications as listed in the BriteSmile handbook were excluded. The

Principal Clinical Investigator Dr. Cyrus Tahmasebi oversaw this study and coordinated data collection and verification.

Subjects in Group A & B attended an orientation meeting at the BriteSmile Center in La Jolla. They completed a medical and dental health history and the consent forms. This was followed by an interview, oral examination and an evaluation of the teeth shade using the Vita Pan Shade Guide. If enrolled, the subject's pre-whitening shade was recorded and photographed using the Polaroid SLR 5 camera. Special attention was paid to keep the lighting conditions constant in the same operating room, as well as maintaining identical settings on the camera. The subjects in group A were then given the BTG pen with instructions to apply the gel twice daily everyday except Sundays for a period of two weeks. The subjects in Group B were instructed to visit the La Jolla BriteSmile Center twice daily to receive supervised application of BTG for two weeks except Sundays. Group A was instructed to contact the Center with any sensitivity issues or any other compliance questions. Group B was evaluated daily.

In Group A the patients were instructed to apply a thin film on teeth numbers 4 through 13 and 20 through 29 and asked not to eat or drink anything for at least 15 minutes post application. Those in Group B had the BTG gel applied directly from the pen by the Clinical investigators at the La Jolla BriteSmile Center and given the same instructions. Those in Group B were evaluated daily for sensitivity and any signs of oral irritations. The shade changes were evaluated at the conclusion of the study using the Vita Pan Shade in the following order of lightest to darkest: B1, A1, B2, D2, A2, C1, C2, D4, A3, D3, B3, A3.5, B4, C3, A4, C4. These shades were then assigned a numerical number of 1 through 16, B1 being #1.

Results

The results of the efficacy were analyzed using the Vita Pan Shade Guide with numerical values of 1 through 16.

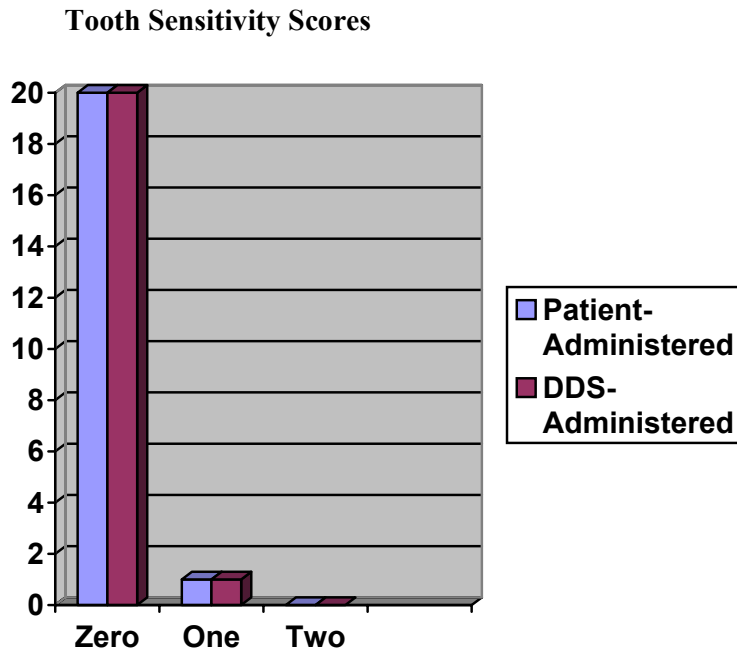
Tables 1 shows the average shade change statistics for groups A and B.

<u>Group</u>	<u>Average Shade Change (total)</u>	<u>Average Shade Change (A3 and darker)</u>
A	4.1 +/- 1.7	4.6 +/-1.6
B	4.0 +/- 1.3	4.3 +/-1.3
	p = 0.29	p = 0.21

These results demonstrate that the BriteSmile To Go product produced an average shade improvement of approximately 4 for a group of patients A3 and darker. This can be compared to an average shade change of 9.3 shades for the BriteSmile one hour whitening treatment for patients A3 and darker. The results of the BriteSmile To Go product are comparable to the results obtained for tray products. See Niederman R, Tantraphol MC, Slinin P, et. al. Effectiveness of Dentist-Prescribed, Home-Applied Tooth Whitening. A Meta Analysis. *J Contemp Dent Pract* 2000;(1)4: 020-036.

Safety was analyzed by evaluating BTG's effect on the oral tissue and by measuring the tooth sensitivity that was reported. The final oral exam evaluated the lips, the palate, the gingival mucosa and surrounding tissue and glands as well as a complete oral cancer screen. The sensitivity was

evaluated by reporting none, mild, moderate or severe with each given a numerical value of 0 to 3 with severe being #3.



No oral irritation was noted on any of the subjects.

Discussion

The efficacy of the BTG 5.25% hydrogen peroxide gel in the pen was measured for both Group A and Group B using the Vita Pan Shade Guide scores. The average shade improvement in both Groups A and B was approximately 4 shades for patients with a baseline shade of A3 or darker. Neither Group reported tooth sensitivity, with the exception of 2 patients who reported possible mild sensitivity experienced only once by each. Every participant in the study noticed a subjective improvement in tooth whiteness and some indicated that they started noticing improvement within days of using the BTG Pen.

The results are significant in both the efficacy and the low incidence of tooth sensitivity. Also, the similarity in shade improvement of both Groups may be indicative of good patient compliance as a result of the ease and convenience of BTG. On an exit interview patients rated the BTG Pen as an 8+ on a scale of 1-10, 10 being the most favorable.

Conclusion

The data from this clinical investigation demonstrate that the BTG Pen is a safe and effective system for whitening teeth, and is an easy-to-use alternative to tray-administered tooth whitening.