

Clinical efficacy report of LIVE PURE DIA whitening gel

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In this study, the effect of the experimental bleaching gel (LIVE PURE DIA Whitening Gel, [LAV, Inc., Gangnam, Korea, Brand: Liveorals]) containing 3% hydrogen peroxide was evaluated. Fifty people used the bleaching gels for half an hour daily. The color was measured at baseline and 3 days, 1 week, 2 weeks after treatment using the Shade eye-NCC colorimeter and Vita Classical Shade Guides organized by value. The shading change of the entire teeth was so large ($P < 0.05$) that it could be easily perceived. (THE JOURNAL OF KOREAN ACADEMY OF OSSEOINTEGRATION 2023;15(1):6-9)

Key words: Bleaching gel, Safety, Effectiveness, Hydrogen peroxide, Clinical study

INTRODUCTION

With the increasing aesthetic demands of the modern society, the desire to improve teeth shades is growing, which has led to the development of aesthetic dentistry¹⁻³. Teeth are highly exposed parts of the body, and their shapes and colors can have significant impact on appearance, which can change first impressions. The factors that cause tooth discoloration can be divided into congenital and acquired. Congenital tooth discoloration can be caused by ingestion of fluoride in concentrations higher than 1.5 parts per million (ppm) during childhood, when teeth are still forming, or by maternal use of antibiotics containing tetracyclines during the prenatal period. Acquired discoloration can be caused by tobacco and food staining, as well as by external impact, where a sudden large force is applied to the tooth, causing the capillaries to become damaged and bleeding to spread to the surrounding tissues, making the blood visible⁴. Currently, hydrogen peroxide is being used as a material for teeth whitening, and the bleaching mechanism has been known as a decolorization process that decomposes and removes organic substances that are attached to the outside of the teeth and cause discoloration through the oxidation of generated oxygen. Teeth whitening can be categorized into three main types: professional whitening performed in the office by a dentist; home whitening performed at home by a patient with a dentist's prescription; and at-home whitening performed by an individual without a dentist's prescription. Professional whitening uses 15% hydrogen peroxide, takes about an hour, and is effective in just one to

two treatments. In the case of professional whitening, distinct effects can be seen within a short period, but due to high concentration, gum damage and dryness symptoms may appear, and if not cared for properly, may not have a lasting effect. In the case of self-whitening, dentists make teeth molds for whitening that fits each individual's teeth, or standardized molds are used. After adding whitening gel, it takes two weeks to whiten the teeth. 3.5~5.4% hydrogen peroxide is used, and the relatively low concentration results in few side effects. In the case of at-home whitening using non-medical products, there are gel types that are placed in trays containing hydrogen peroxide, adhesive types that attach patches to teeth surface, and coating types that are applied to teeth surface. According to the standards of the Korean Ministry of Food and Drug Safety, products containing more than 3% hydrogen peroxide cannot be used, and previously used products have disadvantages such as having to wear a mouth opening device, difficulty in activities due to the adhesion of the patch, and difficulty in adhering hydrogen peroxide to the teeth. In order to improve these shortcomings, this study adopted the method of applying hydrogen peroxide gel to a silicone mouthpiece developed by LAV, Inc. and measured its convenience and efficacy. This study aimed to evaluate the clinical efficacy of a whitening gel containing 3% hydrogen peroxide. Fifty healthy adults wore the mouthpiece with the test whitening gel for 30 minutes daily, and the efficacy of the whitening gel was evaluated by repeated measurements on the third, seventh, and fourteenth day of use VISIA-CR, a facial photography and image analysis program, and Vita Shade Guide.

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MATERIALS AND METHODS

1. Research subjects

For this study, 50 men and women aged 20 to 60 years old were selected for this clinical trial at Live Dental Hospital Incheon, located in Incheon Metropolitan City, and were excluded if they had inappropriate dentition for teeth whitening, resin and porcelain restorations in the anterior teeth, inflamed pulp due to tooth decay or tooth wear, hypersensitivity symptoms due to gingivitis and periodontitis, excessive discoloration due to medication or congenital developmental abnormalities, and if it had not been three years since they had undergone a teeth whitening procedure in the past. The subjects were categorized according to their age as Group A for those in their 20s, Group B for those in their 30s, Group C for those in their 40s, Group D for those in their 50s, and Group E for those in their 60s.

2. Study design

Mouthpieces with gel containing 3% hydrogen peroxide (LIVE PURE DIA Whitening Gel) were used for 2 weeks. Before the test, teeth were brushed and any remaining oral moisture was removed. Teeth were rinsed thoroughly with water as the mouthpieces were removed. Whitening gel was used for 30 minutes daily. Teeth color and shades were evaluated at the point of fifth, seventh, and fourteenth days after use. Each measurement was taken in the same location at the same light level to minimize measurement error. The main ingredients of the whitening gel used in the study are shown in Table 1.

3. Research methods

Subjects were invited to clinic on weekdays during the test period with whitening gel-applied mouthpieces delivered to confirm

its application. Subjects were asked to remove it after 30 minutes. On weekends, subjects were given 2-day supplies of whitening gel and mouthpiece. Two weeks later, they were asked to revisit the clinic at the same time to evaluate the efficacy and side effects by measuring the color in the same way as before the test.

4. Efficacy evaluation

1) Vita Shade Guide

The series of colors was selected as A, B, C, D, and the brightness was selected on a scale of 1~4 to measure the change of teeth color by color contrast.

To measure the change in teeth tone, the Vita Shade Guide (VITA classical shade guide, VIDENT™, CA, USA) was used. The color standard has 16 levels (B1, A1, B2, D2, A2, C1, C2, D4, A3, D3, B3, A3.5, B4, C3, A4, C4) with color tabs referring to Table 2. The closer to 1, the brighter the color, and the closer to 16, the darker, with B1 being 1 and C4 being 16 in points. After each measurement, it is necessary to look at the sky or trees in the distance to relieve color fatigue.

2) Face photo taken with VISIA-CR

VISIA-CR (Canfield Imaging System, USA) was used to image the subjects' faces with a cross-polarized mode. The VISIA-CR is equipped with a specially designed chin rest and forehead fixture to maintain a constant angle during the shoot, and the distance between the subject and the camera is always constant. For each measurement, a strobe mounted inside the device was used to stabilize the shooting

Table 2. Stages of shade by VITA classical Shade Guide

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

Table 3. Color changes with Vita Shade Guide of all teeth by bleaching periods

Group	Time		
	3 days	7days	14 days
A	2.8	5.9	7.1
B	4.6	7.7	7.6
C	5.5	8.1	7.5
D	4.2	6.9	7.8
E	3.9	5.4	7.9
Average	4.2	6.8	7.6
Variance	0.975	1.32	0.097
Standard deviation	0.987	1.149	0.311

Table 1. Whitening gel primary ingredients

LIVE PURE DIA whitening gel	- Hydrogen peroxide 35% - Xylitol - Lettuce extract - Polysorbate 80 - Povidone - Citric acid - Sucralose - Glycerin - Ethanol - Sodium citrate hydrate - Mixed fragrance (apple mint flavor BSA13001) - Polyethylene glycol 400 - Colloidal silicon dioxide - Purified water
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conditions. Changes in teeth color brightness were measured using an image analysis program (Image-Pro Plus, USA), and the mean of V value was earned. V-value is a factor related to brightness, and an increase in V-value means an increase in brightness. The rate of increase in V value was calculated using the formula below.

- Percentage increase in V value (%)

$$= \frac{\text{Measurements after product use} - \text{Measurements before product use}}{\text{Measurements before product use}} \times 100$$

In addition, the percentage of study subjects with an increase in the measurement result after the application of the product was calculated using the formula below.

- Percentage of study subjects with increased V-value (%)

$$= \frac{\text{No. of subjects with improved results}}{\text{Total number of subjects}} \times 100$$

3) Self-reported symptoms and adverse effect assessment

Researchers monitored the subjects for adverse effects and graded them according to severity. If identified, it was further

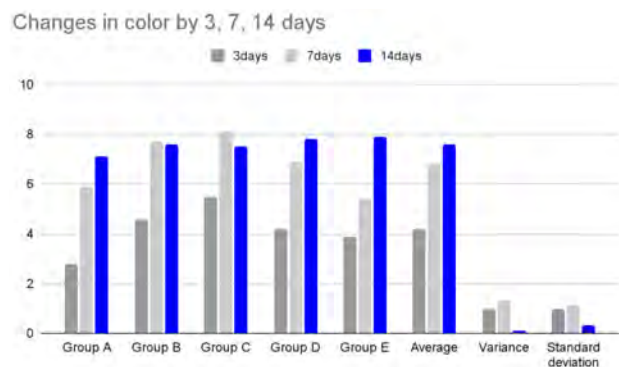


Figure 1. Shade changes by the bleaching procedure is measured using Vita Shade Guide by bleaching periods.

Table 4. In-object effectiveness test results (before and after comparison)

F	Degree of freedom	Probability P
3.458	2, 98	0.041

Probability P (repeated measures ANOVA, Significant: * $P < 0.05$, sphericity assumption).

Table 5. Technical statistics and object-to-in-residence test results (comparison by point in time)

	Before application	3 days after	7 days after	14 days after
AVE $\pm$ STDEV	194.278 $\pm$ 8.536	195.278 $\pm$ 8.632	195.814 $\pm$ 8.722	195.360 $\pm$ 8.706
Probability P	–	0.029*	0.033*	0.046*

Probability P (repeated measures ANOVA with contrast test significant: * $P < 0.05$).

evaluated by a specialist in accordance with the regulations for handling adverse effects.

To evaluate the adverse effects caused by the use of the whitening gel, symptoms were investigated through questionnaires on the 3rd, 7th, and 14th days of use. Symptoms were categorized into three levels: high, medium, and low, with high being unable to continue the experiment, medium being painful but able to continue, and low being irregular mild pain.

EXPERIMENTAL RESULTS

1. Validation

1) Measuring teeth color change over time with Vita Shade Guide

Table 3 and Figure 1 show the amount of shade changes after 3, 7, and 14 days, respectively, using the Vita Shade Guide. There was no significant difference in the hue measurements taken before the whitening experiment, but after 3 days of whitening, there was a significant effect in all groups, but with a difference in degree of whitening between groups. After 14 days, there was no difference between the groups, and all groups showed a significant change with an average change of 7.6 shades.

2) Measurement of teeth color change over time with VISIA-CR

The results of teeth brightness (V-value) measurement using VISIA-CR photo and image analysis program, statistical analysis and percentage increase including average (AVE), variance (VAR) and standard deviation (STDEV) are as follows (Table 4-7, Figure 1, 2).

A within-subject effect test was conducted on V values before

Table 6. Average of individual growth rates (%) for V values

	3 days after	7 days after	14 days after
%	0.931	0.800	0.562

Table 7. Percentage of study subjects with increased V value (%)

	3 days after	7 days after	14 days after
%	76.667	86.010	84.952

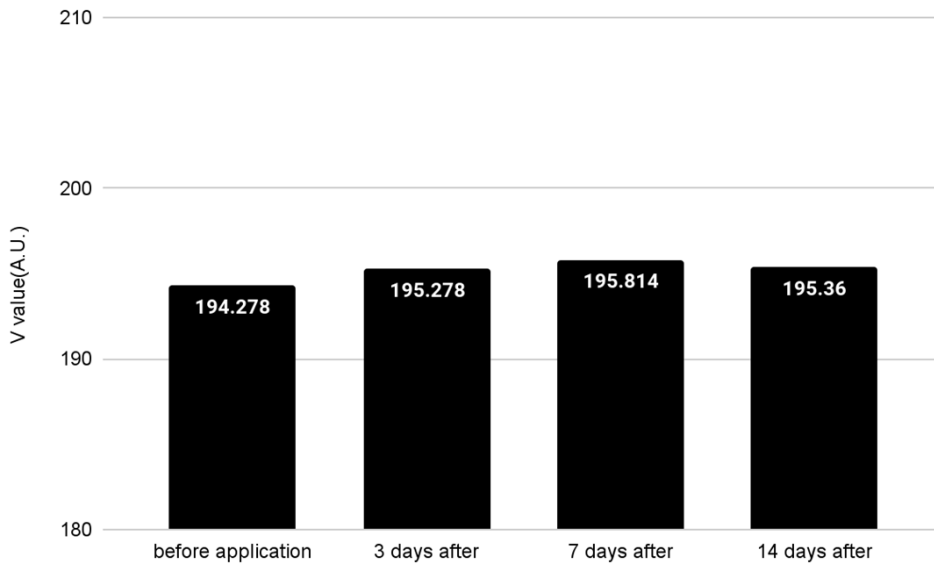


Figure 2. V value measurement result.

and after product application using VISIA-CR photo and image analysis program. The results showed a statistically significant difference ($P < 0.05$) in V values.

The within-subject contrast test showed that V increased at a statistically significant level ($P < 0.05$) after 3 days, 7 days, and 14 days of application compared to before application, with increases of 0.931%, 0.800%, and 0.562%, respectively (Table 4~7, Figure 1, 2).

As shown in Table 7, 76.667%, 86.010%, and 84.952% of the subjects showed an increase in V-value after 3 days, 7 days, and 14 days, respectively.

2. Skin adverse effects

1) What researchers say

Adverse effects were evaluated by researchers and no specific symptoms (adverse effects) related to skin reactions were observed during the study.

CONCLUSION AND SUMMARY

A study was commissioned by LAV, Inc. to conduct an internal trial to evaluate the effectiveness of the LIVE PURE DIA whitening gel made by Liveorals in improving teeth whitening with 50 subjects. After analyzing the measurements of teeth brightness

using Vita Shade Guide, the incremental increase was statistically significant ($P < 0.05$) after 3 days, 7 days, and 14 days of application compared to before application, with an increase of 4.2 shades, 6.8 shades, and 7.6 shades, respectively. According to the analysis of brightness measurements of teeth area using VISIA photo and image analysis program, V value increased at a statistically significant level ($P < 0.05$) after 3 days, 7 days, and 14 days of application compared to before application of the product, with an increase of 0.931%, 0.800%, and 0.562%, respectively. Therefore, it is concluded that LIVE PURE DIA Whitening Gel helps improve teeth whitening after 3 days, 7 days, and 14 days of application. The product also did not cause any significant adverse skin reactions (side effects) during the evaluation period.

REFERENCES

1. Kihn PW. Vital tooth whitening. Dent Clin North Am 2007;51:319-331.
2. Kim SY, Park JU, Kim CH, Yang SE. A clinical evaluation of efficacy of an office bleaching gel containing 30% hydrogen peroxide. J Kor Acad Cons Dent 2010;35:40-50.
3. Kim SY, Park JU, Kim CH, Yang SE. A clinical evaluation of safety of an office bleaching gel containing 30% hydrogen peroxide. J Kor Acad Cons Dent 2010;35:198-210.
4. Haywood VB, Heymann HO. Nightguard vital bleaching. Quintessence 1989;20:173-176.