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Clinical evaluation of three months' nightguard vital bleaching on tetracycline-stained teeth using Polanight 10% carbamide gel: 2-year follow-up study

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Abstract Nightguard vital bleaching (NGVB) has been applied as a safe and effective bleaching procedure with a wide variety of commercial products consisting of carbamide peroxide-based gels, but there have been few reports on tooth bleaching for tetracycline-stained teeth. The purpose of this study was to evaluate the bleaching effects on teeth discolored by tetracycline with 3 months' active treatment, and to investigate the participant satisfaction, the shade stability, and the post-treatment side effects 2 years after the treatment. A custom-made tray with Polanight 10% carbamide peroxide gel was applied to both the incisal and premolar teeth (10 teeth of each participant), and the participants were directed to wear the tray every night over the course of the 3 months. The whiteness–blackness difference (L^*) became lighter within 3 months and the lightness remained until 2 years later. Tooth color changes were remarkable in both redness–greenness difference (a^*) and yellowness–blueness difference (b^*). No obvious shade change or slight darkening was recognized 2 years post-treatment. The means of the color difference (ΔE^*) at 3 months, 6 months, 1 year, and 2 years were 13.74, 14.02, 12.17, and 11.81, respectively. All participants were satisfied with the shade change of their teeth, but three participants complained of slight hypersensitivity. One participant complained of cold or hot pain in daily life until 6 months after the treatment. These side effects were alleviated within 1 year. The results suggested that the standard treatment period of NGVB with Polanight for tetracycline-discolored teeth may be determined to be 3 months.

Key words Vital bleaching · Tetracycline · 3 Months · Polanight

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Introduction

Nightguard vital bleaching (NGVB) was reported by Haywood and Heynmann in 1989.¹ Since then, NGVB has become a popular tooth-bleaching procedure. NGVB has usually been applied as a home bleaching procedure, with a wide variety of commercial products consisting of carbamide peroxide-based gels. Numerous clinical studies have reported the effectiveness of NGVB in tooth bleaching.^{2–6} On the other hand, there have been few reports on the bleaching of tetracycline-stained teeth with NGVB. Tetracyclines belong to a class of broad-spectrum antibiotics, and are well recognized to result in the intrinsic discoloration of tooth enamel when prescribed during tooth development.^{7,8} The bleaching of teeth discolored by tetracyclines has been considered to be a difficult method to achieve good results with, because the bleaching was thought to require long-term treatment and a high gel concentration. Haywood et al.⁹ have reported a 6-month longitudinal bleaching study for tetracycline-discolored teeth using NGVB treatment with 10% carbamide peroxide, and they reported that tetracycline-discolored teeth could be whitened successfully using an extended treatment time, and that the shade stability was maintained for at least 90 months after treatment.^{10,11} Bruce et al.¹² have reported that a 10% concentration of carbamide peroxide has the most advantages and the fewest disadvantages for a 6-month treatment.

On the other hand, there have been few fundamental and clinical research reports about NGVB as a regimen, or on the type of side effects. In Japan, Night-white excel (Discus Dental, Culver City, CA, USA) appeared on the market as a home bleaching agent in 2001, and then HI-LITE Shade up (Shofu, Kyoto, Japan) appeared in 2004. I have evaluated a home bleaching agent, Polanight (SDI, Melbourne, Victoria, Australia), compared with one of the most popular home-bleaching gels, Opalescence (Ultradent Products, South Jordan, UT, USA), using a split-mouth protocol.¹³ Of note, there have been no reports about the bleaching of teeth discolored by tetracyclines using NGVB for Japanese patients. It has been assumed that differences in the ana-

tomic form of teeth or differences in lifestyle between Japanese and other populations might influence a bleaching regimen. For example, because Japan is one of the countries where water fluoridation is not carried out, this may result in enhancement of tooth hypersensitivity. Therefore the treatment period of bleaching should be as short as possible. It is very important to accumulate data on NGVB treatment for teeth discolored by tetracyclines in Japan.

This is the first bleaching study of tetracycline-discolored teeth in Japanese patients. The purpose of this study was to investigate the bleaching effects of 3 months' active treatment, patient satisfaction, and the shade stability and post-treatment side effects 2 years after treatment.

Subjects, materials, and methods

Study population

Japanese female subjects ($n = 10$; 24–28 years old) having moderately to severely tetracycline-discolored teeth without health problems were selected. Written informed consent was obtained from all subjects after the nature and possible risks of the study had been explained.

Bleaching agents

The bleaching agent used was Polanight 10% carbamide peroxide gel (SDI).

Study protocol

Preparation of study casts and individual custom trays

An impression of the maxillary arch was made using the alginate impression material (Aroma Fine DF III; GC, Tokyo, Japan), and a study cast was fabricated using dental stone (Clin stone; KO Dental, Tokyo, Japan). Resin block-out material (~5-mm width and ~2-mm height) was applied on the labial surface to create a reservoir for the carbamide peroxide gel. A professionally constructed soft-type custom-made tray covered the gingiva with a depth of 2–3 mm.

Bleaching steps

Bleaching procedures were performed according to the conventional procedures; that is, one drop of carbamide

peroxide gel was placed into the individual reservoir tray, and the participants were directed to fix the tray every night for 3 months. The participants were asked to neither smoke nor to have strong-colored foods and drinks while the procedures were in progress. The tooth shade was measured at the initial examination, after the 3 months' treatment, 6 months later, 1 year later, and 2 year later with a portable chroma meter (Shofu Shade Eye NCC; Shofu, Kyoto, Japan), and recorded in a preoperative photograph. The right or left canine tooth was subjected to the tooth shade examination. The test tooth (canine) had no extensive restoration, pulpal problems, or any periodontal tissue problems, and was darker than C3 or D3 (class 2 or 3 of Feinman's classification for tetracycline) on the shade Eye NCC before treatment. Participants were asked to record how long the tray was fixed every night, and to record the presence or absence of side effects such as hypersensitivity. Measuring points were designated at least 5 mm above the cervical margin and above the severely discolored bands on the labial surface with maxillary right or left canine teeth. The tooth surface around the measuring points had not undergone any restoration. The data were measured three times and the average value was converted to Commission International d'Eclairage (CIE) Lab units and used for comparison of shade changes between pretreatment and 2 years later.

Statistical analysis

Student's *t*-test was employed for statistical analysis.

Results

Typical bleaching results are shown in Fig. 1 and Fig. 2 (patient no.1). The mean treatment time for the all patients during the 3 month treatment period was 450 h (5 h/night). Obvious shade change was recognized after treatment, and neither obvious shade change nor slight darkening was recognized 2 years after the treatment. The tooth color changes (in Lab-tooth color units) are shown in Table 1. The lightness became lighter and remained at that value until 2 years after the treatment. Tooth color changes were remarkable in terms of both redness ($P < 0.01$) and yellowness ($P < 0.025$). The shade changes and the color difference (ΔE) values are shown in Table 2. Remarkable color changes were observed after 3 months of treatment in all cases.

Table 1. The mean values of Lab-tooth color change

	Pretreatment	Post-treatment	6 Months later	1 Year later	2 Years later
Lightness (L)	59.56 ± 6.41	68.61 ± 5.48	67.66 ± 5.76	66.89 ± 5.38	64.76 ± 5.28 NS
Redness (a)	4.54 ± 2.84	0.10 ± 2.39	0.39 ± 2.56	0.95 ± 2.47	1.34 ± 2.43 *
Yellowness (b)	16.93 ± 2.66	8.82 ± 3.87	7.32 ± 3.46	9.16 ± 3.51	11.38 ± 4.62 **

* $P < 0.01$; ** $P < 0.025$

Data are shown as means ± SD ($n = 10$)

NS, not significant (difference between the post-treatment and 2 years later)

Table 2. Shade changes and color difference (ΔE) values

Participant no.	Pretreatment		Post-treatment		6 Months later		1 Year later		2 Years later	
	Vita		Vita	ΔE	Vita	ΔE	Vita	ΔE	Vita	ΔE
1	C3		C1	16.09	C1	14.18	C1	12.40	C1	12.51
2	D3		D1	13.56	D1	13.19	D2	9.54	D2	8.86
3	C4		D2	11.75	D2	13.86	D2	13.01	D2	12.79
4	C4		D2	18.01	D2	17.49	D2	15.35	D2	15.11
5	D4		D2	19.57	D2	19.48	D2	17.97	D2	16.43
6	C4		C2	10.42	C1	11.83	C2	9.39	C2	8.89
7	C4		C2	17.43	C2	16.89	C2	16.48	C2	15.82
8	D4		D2	11.12	D2	11.21	D2	10.89	D2	10.02
9	D3		D2	11.28	D2	15.01	D2	10.70	D2	11.19
10	C3		C2	8.22	C2	7.11	C2	6.02	C2	6.46
			13.74 \pm 3.79		14.02 \pm 3.53		12.17 \pm 3.64		11.81 \pm 3.32	

$P < 0.01$, significant difference between the ΔE values post-treatment and 2 years later

Fig. 1A–D. An example of the bleaching of tetracycline-stained teeth with Polanight. **A** before treatment, **B** after 3-months' bleaching treatment, **C** 6 months post-treatment, **D** 1 year post-treatment

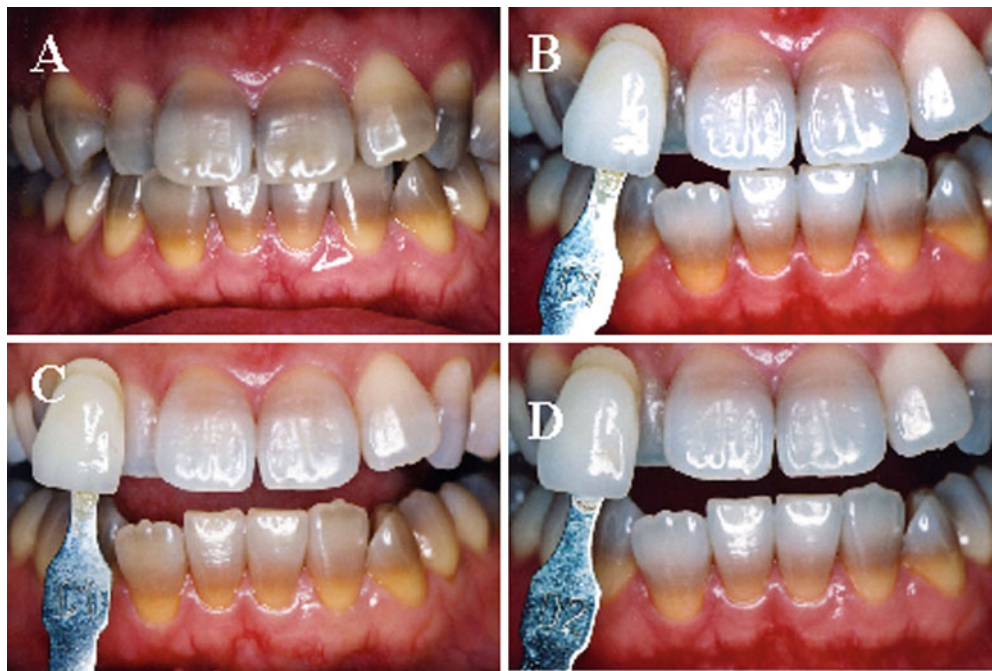


Fig. 2. Status at 2 years post-treatment

There was a significant difference in ΔE tooth color changes between the post-treatment value and that of 2 years after treatment ($P < 0.01$).

All participants were satisfied with the shade change of their teeth; however, three participants complained of hypersensitivity at the end of the 3-month treatment. One participant complained of cold or hot pain in daily life until 6 months after the treatment, and two participants complained of gingival sensitivity and slight hypersensitivity, respectively, in daily life until 6 months after the treatment. These side effects were alleviated within 1 year, and there were no further problems or side effects. The side effects reported by the participants are summarized in Table 3.

Table 3. Side effects reported by participants

	Post-treatment		6 Months later		1 Year later		2 Years later	
	Yes	No	Yes	No	Yes	No	Yes	No
Hypersensitivity with any teeth (1) Slight	1	9	2	8	0	10	0	10
(2) Moderate	0	10	0	10	0	10	0	10
(3) Significant	0	10	0	10	0	10	0	10
Root canals or treatment of nerve on any teeth		10		10		10		10
Gingival sensitivity around any teeth	1	9	1	9	0	10	0	10
Teeth are normally sensitive to heat and cold	1	9	1	9	0	10	0	10
Satisfied with treatment results	10	0	10	0	10	0	10	0

Discussion

Home bleaching has become popular as a valuable method for making teeth whiter and brighter without tooth reduction or side effects. Many products are on the market and their efficacies have been reported. However, there have been few reports of the effects of home bleaching against discoloration caused by tetracyclines. Haywood et al.² reported that 75% whitening efficacy was recognized in tetracycline-stained teeth, using a 10% carbamide peroxide solution with 6 weeks' treatment, in 1994, and they then reported that a 6-months' longer treatment gave an efficacy rate of 86%.⁹ According to their hypothesis, the whitening of tetracycline-discolored teeth may require a whitening treatment longer than 180 days. The results of the present study indicated that 90 days' (3 months') treatment was sufficient for the bleaching of tetracycline-discolored teeth using Polanight 10% carbamide peroxide gel. The tooth color became almost constant after the 3 months' treatment, and there was no remarkable change during the 2-year test period. The mechanism by which bleaching was effective with only 3 months' treatment is not clear, but it may depend on the chemical advantages of the ingredients of Polanight, or on the enamel characteristics of the teeth in Japanese people. Polanight 10% carbamide peroxide gel is a new material that appeared on the market in 2002. In previous studies, we reported that Polanight showed significantly higher ΔL and Δb values than conventional products in the Japanese.¹³

There are many patients who have complained of tetracycline-discolored teeth in Japan, because, when the administration of antibiotics was greatly revised in 1962, tetracyclines and chloramphenicol were selected to be the first choice in Japan. In particular, large amounts of tetracyclines were produced in the 1970s. In the 1980s, the production and consumption of tetracyclines decreased, but tetracyclines were still useful in otolaryngology, and still remain a sizeable market. Some participants in the present study were administered a large amount of various medicines, especially tetracyclines, during the period of tooth formation, when they had had repeated episodes of diseases with high fever.

It was clear that in the Japanese population in the present study, Polanight had few side effects with long-term treatment. One participant in the first half of the 3 months'

treatment and one participant in the second half complained of a gum-related symptom. In regard to hypersensitivity, one subject complained of this in the first half of the treatment period, and two participants did so in the second half of the period. The symptoms were alleviated within 1 year. Moreover, in the interview, there were no problems reported related to cold or hot pain. Thus, no participants complained of side effects 2 years after treatment in this study.

Leonard et al.¹¹ have reported that in 15 participants who completed 6 months' treatment using Opalescence, the median shade change from pretreatment was VITA C4 to C2, respectively. And also Leonard et al.¹¹ reported that 80% of the participants experienced side effects; 6 of 9 males reported side effects, and all 12 females reported side effects. In the present study, three participants experienced slight tooth hypersensitivity until 6 months after the treatment, and one other participant experienced a gum-related symptom. When the treatment period is too long, the perception of hypersensitivity might be somewhat prolonged; therefore, I recommend that the treatment period in the future should be as short as possible. The present study showed that it is possible to bleach the tetracycline-discolored teeth of Japanese using Polanight for 3 months. To make this procedure a general method, it is necessary to accumulate more data.

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