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# Clinical Evaluation of New Bleaching Product "POLA NIGHT" on Japanese population

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(Abstract) up to 250 words

The home bleaching technique has been applied as a safe and effective bleaching procedures. Many manufacturers are now marketing home tooth bleaching products. The purpose of this study was to compare a new bleaching product, Pola Night (SDI Ltd., Australia) with a widely used home bleaching product, Opalescence (Ultradent, USA). Fifty-eight healthy Japanese volunteers (18~47 years of age) were selected. Using a simultaneous split mouth protocol, a custom tray was applied to maxillary right anterior teeth with Pola Night and left anterior teeth with Opalescence, respectively. Tooth shades of maxillary canines were measured with a portable chromameter (Shade Eye Ex, Shofu, Japan) at the examination and at 4 weeks (2 weeks bleaching and 2 weeks after treatment). Tooth shade changes were analyzed using CIE Lab units. Total number of the subjects were 58. Statistical analysis was performed using Student's T-test. Means of $\Delta L^*$, $\Delta a^*$ and $\Delta b^*$ were 4.00, -1.28 and -7.53 for Pola Night, and 2.54, -0.99 and -5.56 for Opalescence, respectively. Mean of $\Delta E$ were 9.23 and 7.78 for Pola Night and Opalescence, respectively. Both agents indicated significant bleaching effects by the treatment. The new product, Pola Night, showed significant differences in $\Delta L^*$($p<0.05$) and $\Delta b^*$($p<0.005$), while a* value did not show significant difference between them. Both bleaching products, Pola Night and Opalescence, were considered effective in home bleaching. Pola Night seemed to be more effective than

Opalescence.

(Introduction)

It is still common wish in human beings to achieve beautiful dentition. Since vital bleaching has been reported as a conservative measure to improve the esthetics of discolored tooth[1], curtailments and selections resulted in the improvement of this technique. Home bleaching, first reported in 1989 [2], showed rapid spread all over the world, because of many advantages including simple procedure and possibility of time- and cost-saving which can be beneficial for dentists and patients.

Many products are available in the market and many articles can be found in journals. In the past, there were many investigation to biological factor, such as influences to filling materials [3-6], tooth hard tissues [7,8] or oral soft tissues [9,10]. Recently, investigations to an environmental factor, such as treatment time [11,12], comparison with bleaching gel and oral bacteria [13], influence with tobacco smoking [14], has also increased. The data about long-term observation have been also accumulated [15,16].

On the other hand, few fundamental and clinical research reports on bleaching for Japanese has been published [17]. In Japan, single product, Night White Excel, was certified and approved as a home bleaching agent by the Ministry of Health and Welfare in 2001. To popularize the bleaching technique,

it is important to accumulate the data about home bleaching.

This study is the first report to investigate the clinical effect to Japanese patient, compared with the new home bleaching agent "Pola Night" and one of the most popular home bleaching gel, Opalescense, by split mouth protocol employing 2 agents within the same tooth arch.

(Materials and methods)

1. Study population

Fifty-eight Japanese volunteers (16 males and 42 females), ranging from 18 to 47 were randomly selected from the patients visiting a private dental clinic, and involved in this research. Mean age was 30.41. Written informed consent was obtained from all patients after the nature and possible risks of their voluntary participation had been explained. Periodontal check-up and initial treatment for oral hygiene, and caries treatment have been accomplished prior to initiation of the bleaching procedure according to the conventional process.

2. Bleaching agents

The bleaching agents used in the study were Pola Night 10% carbamide peroxide gel (SDI Ltd., Australia) for the test side, and Opalescense 10% carbamide peroxide gel (Ultradent, USA) for the control side.

2. Study protocol

Stone model was made from individual impression. Resin block out material was applied on the labial surface to create reservoir for carbamide peroxide gel. Professionally made soft-type custom tray was supplied to each patient and the procedure was completed by the split mouth protocol.

Pola Night was applied on the right maxilla from the central incisor to the second premolar as the test side, Opalescense on the left as the control side. It was confirmed to the subjects repeatedly. Subjects were directed to wear bleaching tray every night (overnight bleaching method) for 2 weeks in the study.

Tooth shade was taken at the initial examination and 4 weeks later including 2-week treatment and 2-week rest. Right and left canine were subjected for the tooth shade measurement, representing the test side and the control side, respectively. Portable chromameter (Shofu Shade Eye NCC, Shofu, JAPAN) was employed for the measurement. Measurement was accomplished by single examiner. Measuring point was designated at 5 mm above the cervical margin on the labial surface. The point was adjusted mesio-distally when a filling existed.

The data was converted to CIE Lab unit and used for comparison of the shade change between the pre-treatment and post-treatment. Student' t-test was employed for statistical analysis.

Interview to the subjects was also performed to investigate

any unpleasant feelings during and after the treatment. Hypersensitivity of tooth and gingival irritation were recorded.

(Results)

$\Delta E$ value was employed for comparison of total shade change. $\Delta E$ of the test group (Pola Night) and the control group (Opalescence) were $9.23 \pm 4.30$ and $7.78 \pm 5.58$, respectively. $\Delta E$ of Pola Night seemed to be higher than that of Opalescence while no significant difference can be found between $\Delta E$ of Pola Night and that of Opalescence.

Mean values of L*a*b* were shown in Table 1. L*, a* and b*values before and after the treatment is shown in Fig. 2, 3 and 4. $\Delta L$ and $\Delta b$ of the test group (2.60 and 7.53 for Pola Night) showed greater change compared with those of the control group (2.00 and 5.62 for Opalescense), while $\Delta a$ did not. Student' t-test revealed significant differences about $\Delta L$ ($p<0.05$) and $\Delta b$ ($p<0.01$), respectively. No significant difference can be found about $\Delta a$.

Hypersensitivity of tooth and gingival irritation were summarized in Table 2. A few patients reported slight reaction excepting 1 case with severe hypersensitivity. Number of the reaction reported was fewer for Pola Night than for Opalescence. Pola Night was considered to be a less-irritative material with low possibility of any reaction to oral tissues.

(Discussion)

Home bleaching technique has become popular as an valuable method for those who wish to have whiter and brighter teeth with no tooth reduction. This procedure has brought dramatic improvements to many patients with few side effects. Many articles have been published about its efficacy [18-20]. Many new products with various concentrations of carbamide peroxide are introduced to the market. Pola Night 10% carbamide peroxide gel is the newest material introduced in 2002.

Considering the results of the study that $\Delta L$ and $\Delta b$ with Pola Night was significantly higher than those with Opalescence, It was suggested that Pola Night seemed to have greater potential of improvement of esthetics on discolored teeth for Japanese.

While $\Delta a$ showed no significant difference between Pola Night and Opalescence, bleaching procedure did not affect the a* value. This tendency is same as previous studies [17,21]. $\Delta a$ cannot be considered as an important factor because patient's main concern is the change of $\Delta L$ and $\Delta b$, not the change of $\Delta a$.

Pola Night showed excellent results about side effects. Fluoride released from the bleaching gel may help stabilization of crystals in enamel surface to reduce post-operative hypersensitivity. Neutral pH ensures the full release of the peroxide without jeopardizing patient comfort. High water content, addition of Chitosan may also act to reduce hypersensitivity. No irritation nor inflammation of gingiva

was observed during the experimental period. high molecular weight thickener reduces the tacky feeling and drying effect of the gel, contributing less irritative to gum. Chitosan, added in the gel, may have some antibacterial property to inhibit plaque.

Moreover, many subjects evaluated the taste of Pola Night excellent.

(Conclusion)

While Pola Night and Opalescence are considered as effective home bleaching products, Pola Night showed significantly higher values of $\Delta L$ and $\Delta b$ than Opalescence, in concern of the improvement of esthetics of teeth in Japanese.

(Acknowledgment)

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(Legends)

Table 1 Mean value of L*a*b*

Table 2 Summery of Hypersensitivity and Gum Irritation

Fig. 1 Pola Night parsonal kit contains 10 X 1.3g sylinges and accessories.

Fig. 2 Mean L* value

Fig. 3 Mean a* value

Fig. 4 Mean b* value

Table 1 Mean values of L*a*b*

| | Polanight | | Opalescense | |
|---|---|---|---|---|
| | EXAM | 1M | EXAM | 1M |
| L* | 68.70 (3.89) | 72.70 (3.49) | 69.10 (3.48) | 71.70 (2.87) |
| a* | 0.52 (1.18) | -0.76 (0.99) | 0.55 (1.15) | -0.44 (1.15) |
| b* | 15.39 (3.73) | 7.86 (4.17) | 15.09 (3.71) | 9.47 (3.68) |

EXAM: at initial examination, 1M: at 1 month, ( ): Standard Deviation,

Fig. 2 Mean L* value

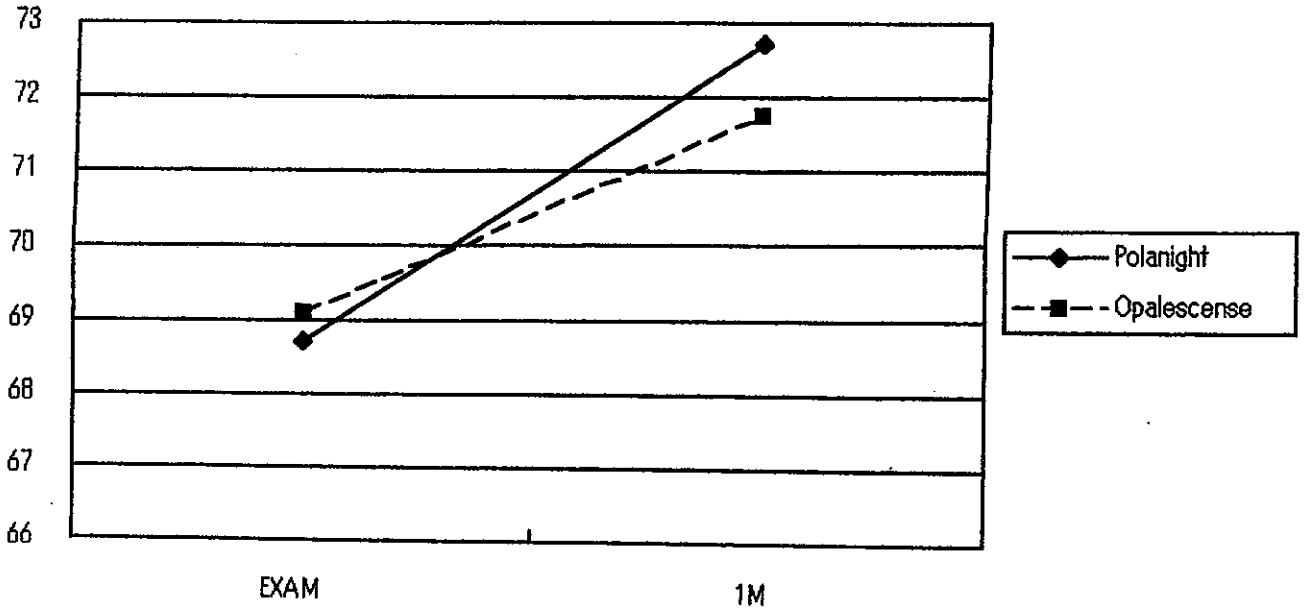

Fig. 3 Mean a* value

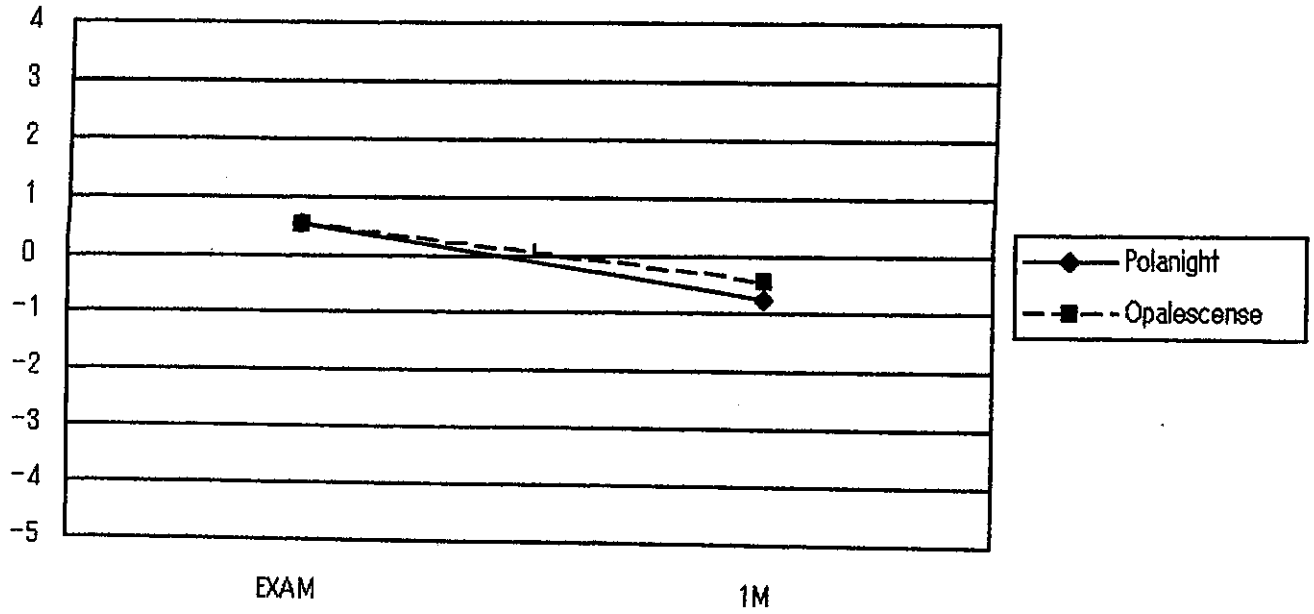

Fig. 4 Mean b* value

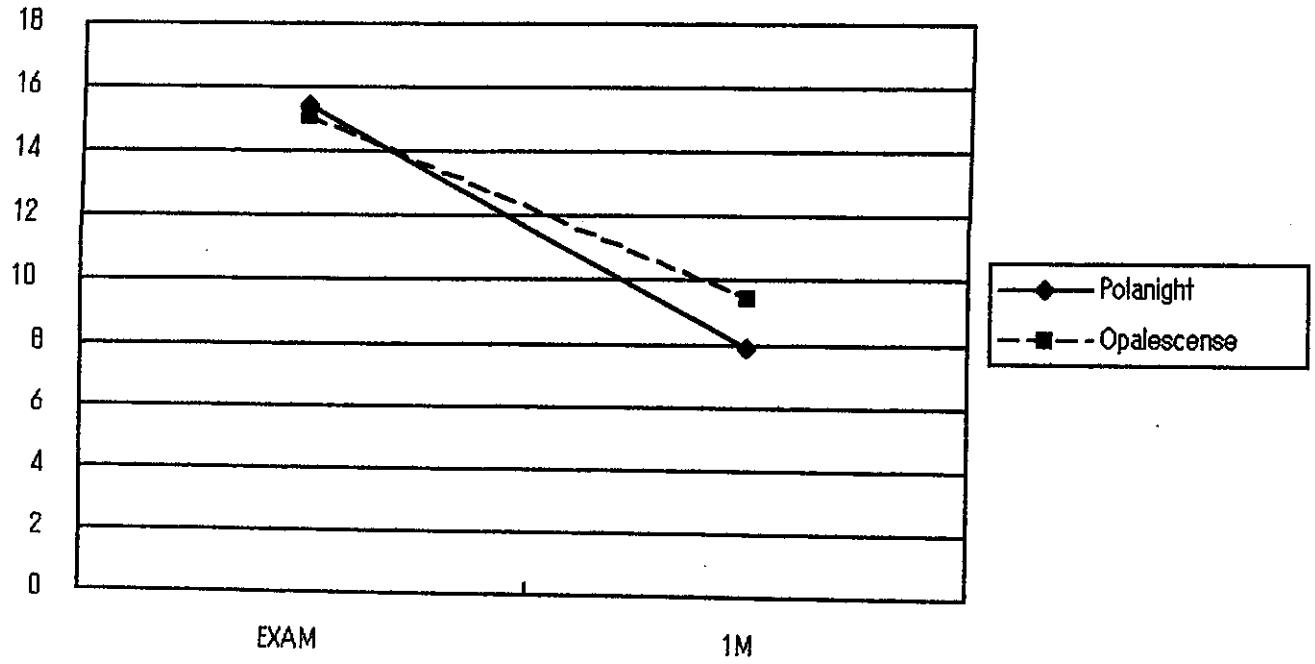

Table 2 Summary of Hypersensitivity and Gum Irritation

| | Hypersensitivity | | Gum Irritation |
|---|---|---|---|
| | Slight | Severe | |
| Polanight | 2/58 | 0/58 | 0/58 |
| Opalescence | 8/58 | 1/58 | 2/58 |

comparisons, specimens were not removed from the molds after polymerization as well. Because the molds were white, this influenced the results by obtaining higher values against a black background, which led to lower TP values. Another technical limitation was that the spectrophotometer used was a contact-type device; this emphasized the first-mentioned limitation due to higher edge-loss error as compared to non-contact-type devices.

Translucency generally showed a tendency to increase after polymerization, but these values were much lower than changes in color. An increase in $TP_{76}$ higher than 1 was recorded for nine shades (ten shades for $TP_{00}$), while a $\Delta TP_{76}$ and $\Delta TP_{00}$ of more than 2 were observed for three shades.

## Conclusion

Within the limitations of this study, polymerization-dependent changes in color were highly varied. The majority of shades showed polymerization-dependent differences in color higher than the $\Delta E_{76} = 3.7$ and $\Delta E_{00} = 3.1$. The composites tested became darker and less chromatic after polymerization. The very strong correlation ($r > 0.97$) between the two color-differences formulae indicates that the limitsions of the CIELAB system do not appear to be a problem when evaluation dental composites; however, the recorded differences between $\Delta E_{76}$ and $\Delta E_{00}$ values stress the importance of data conversion. The translucency parameter was highly varied. *TP* values generally increased after polymerization by light activation.

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ORIGINAL ARTICLE

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# Clinical evaluation of a new bleaching product "Polanight" in a Japanese population

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**Abstract** Home bleaching techniques have been applied as a safe and effective bleaching procedure. Many manufacturers are now marketing home tooth-bleaching products. The purpose of this study was to compare a new bleaching product, Polanight (PN) with a widely used home bleaching product, Opalescence (OP). Fifty-eight healthy Japanese volunteers of both sexes (18 to 47 years of age) were selected. Using a simultaneous split-mouth protocol, custom-made trays with PN and OP were applied to the maxillary right anterior teeth and left anterior teeth, respectively. The shades of the maxillary canine teeth were measured with a portable chromameter (Shade Eye Ex) at the first examination and at 4 weeks (after 2-week bleaching and 2-week rest). Tooth shade changes were analyzed using the Commission Internationale d'Eclairage (CIE) Lab units. Means of whiteness-blackness difference ($\Delta L^*$), redness-greenness difference ($\Delta a^*$), and yellowness-blueness difference ($\Delta b^*$) were 4.00, –1.28 and –7.53 for PN, and 2.54, –0.99, and –5.56 for OP, respectively. Means of color difference ($\Delta E^*$) were 9.23 and 7.78 for PN and OP, respectively. Treatment with either agent demonstrated significant bleaching effects produced by the treatment. The new product, PN, showed significant differences in $\Delta L^*$ ($P < 0.05$) and $\Delta b^*$ ($P < 0.005$), but not in the redness-greenness ($a^*$) value when compared with OP. Bleaching with PN was considered more effective than that with OP in the young patient group and in the women.

**Key words** Clinical evaluation · Vital bleaching · Color change · CIE Lab scale · Japanese

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## Introduction

It is still a common wish in human beings to achieve beautiful dentition. Since vital bleaching has been reported as a conservative measure to improve the esthetics of discolored teeth,[1] curtailments and selections have resulted in the improvement of this technique. Home bleaching, first reported in 1989,[2] has spread rapidly all over the world, because of the many advantages, including the simple procedure and the possibility of time- and cost-saving, which can be beneficial for both dentists and patients.

Many products are available on the market and many pertinent articles can be found in journals. In the past, there were many investigations of biological factors, such as the effects of the whitening agents on filling materials,[3–6] hard tooth tissues,[7,8] and oral soft tissues.[9,10] Recently, investigations of environmental factors, such as treatment time,[11,12] comparisons of effects of bleaching gels on oral bacteria,[13] and the effects of tobacco smoking,[14] have also increased. Data on long-term observations have also been accumulated.[15,16]

On the other hand, few fundamental and clinical research reports on tooth bleaching for Japanese have been published.[17] In Japan, a single product, Night White Excel (Discus Dental, CA, USA), was certified and approved as a home bleaching agent by the Ministry of Health and Welfare in 2001. To popularize the bleaching technique, it is important to accumulate data about home bleaching.

This study is the first report to investigate the clinical effect of home tooth bleaching on Japanese patients, comparing a new home tooth bleaching agent, Polanight (PN; SDI, Sydney, Australia) with one of the most popular home bleaching gels, Opalescence (OP; Ultradent, UT, USA), by a split-mouth protocol employing the two agents within the same tooth arch.

## Subjects, materials, and methods

### Study population

Fifty-eight Japanese volunteers (16 men and 42 women), ages ranging from 18 to 47 years, were randomly selected from the patients visiting a private dental clinic, to be involved in this research. The mean age was 30.4 years. Written informed consent was obtained from all patients after the nature and possible risks of their voluntary participation had been explained. Periodontal check-up and initial treatment for oral hygiene, and caries treatment were accomplished prior to the initiation of the bleaching procedure, according to conventional procedures.

### Bleaching agents

The bleaching agents used in the study were PN 10% carbamide peroxide gel for the test side, and OP 10% carbamide peroxide gel for the control side.

### Study protocol

A stone model was made from each individual impression. Resin blockout material was applied on the labial surface to create a reservoir for the carbamide peroxide gel. A professionally made soft-type custom-made tray was supplied to each patient and the procedure was completed by the split-mouth protocol.

PN was applied on the right maxilla, from the central incisor to the second premolar as the test side, and OP was applied on the left as the control side. The subjects were directed to wear the bleaching tray every night (overnight bleaching method, 6 to 8 h) for 2 weeks, as described in the manufacturers' manuals in the study.

Tooth shade was taken at the initial examination and 4 weeks later (i.e., after 2-week treatment and 2-week rest). Right and left canines were subjected to the tooth shade measurement, representing the test side and the control side, respectively. A portable chromameter (Shofu Shade Eye NCC, Shofu, Kyoto, Japan) was employed for the measurements, which were carried out in all patients by a blinded examiner. Patients who smoked were asked not to smoke from the time that initial treatment check-up procedures were carried out until tooth shade measurement was done. The measuring point was designated at 5 mm above the cervical margin between the enamel and cementum on the labial surface. The point was adjusted mesio-distally when a filling existed.

The data were measured three times and the average was converted to the Commission Internationale d'Eclairage (CIE) Lab units and used for comparison of shade changes between pre-treatment and post-treatment. Student's *t*-test was employed for statistical analysis.

The subjects were also asked about any unpleasant feelings during and after the treatment. Any tooth sensitivity of tooth and/or gingival irritation was recorded.

## Results

The color difference (ΔE*) value was employed for comparisons of total shade change. The ΔE values of the test side (PN) and the control side (OP) are shown in Table 1. ΔE of PN was higher than that of OP, although there was no significant difference between ΔE of PN and that of OP. Whiteness-blackness difference (ΔL*) and yellowness-blueness difference (Δb*) of the test side (4.00 and −7.53, respectively) showed greater change compared with these values of the control side (2.54 and −5.56, respectively), while redness-greenness difference (Δa*) did not show any change. Student's *t*-test revealed significant differences for ΔL* ($P < 0.05$) and Δb* ($P < 0.005$), respectively. No significant difference was found for Δa.

The influence of age was also investigated. The average age of the subjects was 30 years, so they were divided into two groups, a young group (18–30 years; $n = 32$) and an older group (31–48 years; $n = 26$). The results are shown in Table 2. In the young group, ΔE of PN was higher than that of OP, and a significant difference was found between them ($P < 0.025$). Further, ΔL* and Δb* values of the test side (4.36 and −7.66, respectively) showed greater change compared with these values of the control side (2.88 and −6.03, respectively), while Δa did not show any change. ΔL* ($P < 0.05$) and Δb* ($p < 0.025$) showed significant differences between PN and OP. No significant difference was found for Δa*. On the other hand, in the older group, neither ΔE*, ΔL*, Δa*, nor Δb* showed significant changes. These data indicated that bleaching with either agent was effective for both groups, while PN was more effective than OP in the young subjects.

**Table 1.** Comparison of the bleaching effects of Polanight (SDI) and Opalescence (Ultradent)

| Initial value | | | | Treated[a] | | | |
|---|---|---|---|---|---|---|---|
| | Polanight | Opalescence | | | Polanight | Opalescence | |
| L* | 68.70 ± 3.89 | 69.10 ± 3.48 | NS | ΔL* | 4.00 ± 4.05 | 2.54 ± 3.19 | * |
| a* | 0.52 ± 1.18 | 0.55 ± 1.15 | NS | Δa* | −1.28 ± 1.20 | −0.99 ± 0.99 | NS |
| b* | 15.39 ± 3.73 | 15.09 ± 3.71 | NS | Δb* | −7.53 ± 3.42 | −5.56 ± 3.32 | ** |
| | | | | ΔE* | 9.23 ± 4.30 | 7.78 ± 5.59 | NS |

NS, not significant; * $P < 0.05$; ** $P < 0.005$ ($n = 58$)
Data values are shown as means ± SD
[a] Data are shown as differences between initial values and values after treatment

**Table 2.** Influence of age on the bleaching effects of Polanight and Opalescense

| | Initial value | | | Treated[a] | | | |
|---|---|---|---|---|---|---|---|
| | Polanight | Opalescence | | | Polanight | Opalescence | |
| Young group[b] ($n$ = 26) | | | | | | | |
| L* | 68.97 ± 2.86 | 69.50 ± 3.09 | NS | ΔL* | 4.36 ± 2.76 | 2.88 ± 2.83 | * |
| a* | 0.25 ± 0.90 | 0.51 ± 1.28 | NS | Δa* | −1.12 ± 0.99 | −0.98 ± 0.95 | NS |
| b* | 14.73 ± 3.65 | 14.61 ± 3.11 | NS | Δb* | −7.66 ± 2.69 | −6.03 ± 2.84 | ** |
| | | | | ΔE | 9.22 ± 3.10 | 7.34 ± 2.90 | ** |
| Older group[c] ($n$ = 32) | | | | | | | |
| L* | 68.37 ± 4.90 | 68.71 ± 3.92 | NS | ΔL* | 2.86 ± 4.71 | 2.00 ± 3.74 | NS |
| a* | 0.85 ± 1.40 | 0.60 ± 1.01 | NS | Δa* | −1.20 ± 1.43 | −0.77 ± 1.13 | NS |
| b* | 16.20 ± 3.74 | 15.60 ± 4.33 | NS | Δb* | −6.67 ± 3.59 | −4.96 ± 4.07 | NS |
| | | | | ΔE* | 9.24 ± 5.51 | 8.32 ± 7.75 | NS |

NS, not significant; * $P < 0.05$; ** $P < 0.025$
Data values are shown as means ± SD
[a] Data are shown as differences between initial values and values after treatment
[b] Young group, age 18 to 30 years
[c] Older group, 31–48 years

**Table 3.** Influence of sex on the bleaching effects of Polanight and Opalescence

| | Initial value | | | Treated[a] | | | |
|---|---|---|---|---|---|---|---|
| | Polanight | Opalescence | | | Polanight | Opalescence | |
| Men ($n$ = 16) | | | | | | | |
| L* | 68.52 ± 4.12 | 67.95 ± 4.69 | NS | ΔL* | 4.17 ± 4.23 | 2.74 ± 4.71 | NS |
| a* | 0.80 ± 1.53 | 0.83 ± 1.54 | NS | Δa* | −1.25 ± 1.51 | −1.01 ± 1.18 | NS |
| b* | 15.01 ± 4.83 | 14.37 ± 5.37 | NS | Δb* | −5.78 ± 3.19 | −4.96 ± 4.32 | NS |
| | | | | ΔE* | 7.96 ± 4.31 | 7.66 ± 3.87 | NS |
| Women ($n$ = 42) | | | | | | | |
| L* | 68.76 ± 3.84 | 69.59 ± 2.83 | NS | ΔL* | 3.94 ± 4.03 | 2.46 ± 2.45 | * |
| a* | 0.41 ± 1.02 | 0.44 ± 0.97 | NS | Δa* | −1.29 ± 1.08 | −0.98 ± 0.93 | NS |
| b* | 15.54 ± 3.28 | 15.29 ± 3.06 | NS | Δb* | −8.19 ± 3.30 | −5.79 ± 2.88 | ** |
| | | | | ΔE* | 9.71 ± 4.25 | 7.82 ± 6.15 | NS |

NS, not significant; * $P < 0.05$; ** $P < 0.005$
Data values are shown as means ± SD
[a] Data are shown as differences between initial values and values after treatment

The influence of sex on the bleaching effect was also investigated. Data for men ($n$ = 16) and women ($n$ = 42) were analyzed; the results are shown in Table 3. Both agents were effective for bleaching, but no significant differences were detected between them in the men. However, ΔL* and Δb* values showed significant differences between the two agents in the women; ΔE of PN was higher than that of OP, although no significant difference was found between them. The results indicated that bleaching with PN was more effective in the women than in the men.

The number of subjects with complaints of tooth sensitivity or gingival irritation, are shown in Table 4. A few subjects complained about tooth sensitivity and gingival irritation, but none of the subjects discontinued the bleaching treatment with either of the agents. The number of complaints reported was less for PN than for OP. PN was considered to be a less irritative material with a low possibility of causing any reaction by oral tissues.

## Discussion

Home bleaching techniques have become popular as a valuable method for those who wish to have whiter and brighter teeth without the removal of hard dental tissues. This procedure has brought dramatic improvements to many people, with few side effects. Many articles have been published about its efficacy.[18–20] Many new products, with various concentrations of carbamide peroxide, have been introduced to the market. PN 10% carbamide peroxide gel is the newest material, introduced in 2002.

The results of our study, showing that ΔL* and Δb* were significantly higher for PN compared with OP, suggested that PN seemed to have greater potential for improvement of the esthetics of discolored teeth in Japanese.

Regarding the efficiency of bleaching, the young group and the women showed better results compared with the older group and the men, respectively.

**Table 4.** Cases of tooth sensitivity and gingival irritation

| | Sensitivity | Gingival irritation |
|---|---|---|
| Polanight | 2/58 | 0/58 |
| Opalescence | 9/58 | 2/58 |

While Δa* showed no significant difference between the two products tested, the bleaching procedure did not affect the redness-greenness (a*) value. This tendency is the same as that reported in previous studies.[17,21] Δa* cannot be considered as an important factor, because the main concern of the patient is the change of ΔL* and Δb*, not the change of Δa*.

PN showed excellent results as far as side effects were concerned.

Leonard et al.[22] and Haywood et al.[23] reported tooth sensitivity and gingival irritation associated with nightguard vital bleaching with Gly-oxide (Smith Kline Beecham, CA, USA) and Proxigel (Reed & Carnrick, NJ, USA). In these reports, a high percentage of participants experienced side effects (tooth sensitivity and/or gingival irritation) during treatment. On the other hand, the side effects of the two products tested in the present study were negligible. This result may be reflect improvement of the ingredients; however, information about the ingredients of the two products has not been well publicised.

No irritation or inflammation of the gingiva was observed during the experimental period in our study (during treatment or the 2-week rest). The use of a high-molecular-weight thickener may have reduced the tacky feeling and drying effect of the PN gel, making it less irritative to the gingiva. Also, chitosan, added to the PN gel, may have some antibacterial properties to inhibit plaque.

## Conclusion

In regard to the improvement of tooth esthetics in Japanese, Polanight and Opalescence are both considered to be effective home bleaching products; however, Polanight showed significantly higher values for ΔL* and Δb* than Opalescence, especially in the young patients and in women.

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ORIGINAL ARTICLE

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# Anterior crossbite in the primary dentition: proposal for a new analytical method in children

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**Abstract** The aim of this study was to clarify the features of profiles of patients with anterior crossbite in early childhood, using a new method of analysis. Lateral cephalograms of 139 (68 males; 71 females) untreated child patients with anterior crossbite in the primary dentition were assessed. The patients were aged from 3 to 5 years. To evaluate disharmony between the maxilla and the mandible, a proprietary calculating system, the Theoretical Individualized Profile drawing System (TIPS), was applied. Using this system, individualized standard cephalometric values were obtained for normal occlusion. This standard profile, which was harmonized with the cranial base structure of each patient, was compared with the child's original profile. The sizes of the mandibles in the children with anterior crossbite, subclassified into three age groups (3, 4, and 5 years) were greater, both horizontally and vertically, than those in the mean profiles derived from TIPS. The vertical size of the maxilla was smaller than that derived from TIPS in the patients aged 3 years. In contrast, in the patients aged 5 years, the vertical size of the maxilla was larger than that derived from TIPS. These results suggest that, in children with anterior crossbite, the vertical growth of the maxilla is closely related to the variation of morphological conditions with development.

**Key words** Analysis · Diagnosis · Anterior crossbite · Primary dentition · Growth

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## Introduction

### Background

There are highly complex relationships between the cranial base structure and the maxillofacial components. These relationships have been reported by Hasund and Böe,[1] Järvinen,[2] and Senger.[3] On the basis of these relationships, a table of floating norms was designed for evaluating the individual skeletal patterns of young adult patients. As a guide for early diagnosis and treatment planning in child patients, Tollaro et al.[4] attempted to determine floating norms for the assessment of individual craniofacial patterns in the primary dentition period, computing floating norms from subjects aged 5.67 ± 0.82 years.

At the growth stage of the craniofacial structures, there are a number of difficulties associated with the clarification of the relationship between the cranial base structure and the maxillofacial components. Tanabe et al.[5] used the magnitude of the cranial base angle to categorize individual profiles with normal occlusion. Using multivariate analysis, they clarified the relationships between the cranial base angle and the morphological variations of maxillofacial components undergoing growth. With the results, they attempted to construct theoretical models of individualized skeletal profiles of children with normal occlusion, naming the process the Theoretical Individualized Profile drawing System (TIPS).

A TIPS was prepared from the database of the Japanese Society of Pediatric Dentistry,[6] which consisted of data on 122 children with normal occlusion in the primary dentition (63 males and 59 females). TIPS was designed to calculate the standard shape and size of a cephalometric profile with normal occlusion from the cranial base angle and anterior cranial base length of each child patient. In the present study, this system was used to obtain a computed maxillofacial component that was harmonized with the patient's cranial base structure.

Susami et al.[7] reported a high incidence of anterior crossbite in the primary dentition in Japanese children. Opinions