An in vivo spectrophotometric evaluation of Vivera® and Essix® clear thermoplastic retainer discolouration

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Aim: To assess the in vivo colour alterations of two different clear thermoplastic retainers.
Methods: Thirty patients were randomly allocated into two Groups (N = 15) following the completion of active orthodontic treatment. Group 1 received Vivera® and Group 2 Essix® C+ thermoplastic retainers. Each patient was provided with two fabricated retainers (one for use and the other to serve as a control). The CIELAB parameters of the patients' upper central incisors were measured with a SpectroShade™ spectrophotometer immediately after retainer placement (T_0) and again after 15 days (T_1), one month (T_2) and three months (T_3). The measurements were also performed on teeth without the retainer in place. ΔE differences were calculated.
Results: ΔE changes from T_0 to T_1, T_2 or T_3 showed no statistically significant differences between Groups 1 and 2 within any combination of measurements or teeth. $\Delta E_{(T3\text{-}T0)}$ changes for used retainers were 1.55 times higher than control appliances (p = 0.002) and 1.44 times higher than for teeth-only (p = 0.004). For used retainers, changes between T_3 and T_0 were 1.56 times higher than between T_1 and T_0 and 1.47 higher than between T_2 and T_0 ($p < 0.001$). There were no statistically significant differences in ΔE between teeth 11 and 21.
Conclusions: Used retainers exhibited greater colour change than control appliances or teeth-only readings, and increased commensurate with the duration of use. Vivera® and Essix® retainers exhibited similar colour stability. All differences observed were considered clinically acceptable ($\Delta E < 3.7$), although prolonged use could cause clinically significant colour changes.
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Introduction

Numerous orthodontic retention protocols and devices have been proposed for post-treatment change minimisation.[1] While removable retainers are preferable compared with fixed retainers, particularly in relation to oral hygiene, compliance and prolonged use are required by the patients.[2] In order to increase patient acceptance of removable appliances, clear thermoplastic retainers have been presented as a comfortable, aesthetically pleasing and economical alternative to conventional removable retainers.[3] Several materials are currently available for the manufacture of thermoplastic retainers. While thermoplastic materials can provide aesthetic

advantages and patient comfort during orthodontic retention, their physical and chemical properties may be compromised during oral use.[4] Several studies have demonstrated changes in durability and wear resistance after only a few months of intraoral wear.[5] Polyurethane, the basic polymeric component of Vivera® retainers, is not an inert material and is affected by heat, moisture, and prolonged contact with oral enzymes.[6] Moreover, the colour stability of polyurethane has been shown to be affected in vitro by different staining solutions, such as coffee, tea and red wine.[7] From an aesthetic point of view, the colour stability and transparency of thermoplastic material during full-time retainer use remains an important consideration for patients and clinicians.

The aim of the present study was to assess the *in vivo* colour alterations in two different types of clear thermoplastic retainers. The null hypothesis was that there would be no statistically significant difference in CIE colour parameters L*, a* and b* of retainer material before and after intraoral exposure.

Materials and methods

The initial study sample consisted of 30 patients, consecutively selected from October 2013 to November 2015 from a group who completed active orthodontic treatment. All subjects fulfilled the following criteria:

- All received comprehensive orthodontic treatment using either fixed or Invisalign® appliances in both dental arches.
- There was an absence of plaque accumulation and gingival inflammation after removal of orthodontic appliances.
- There were no dental caries, prosthetic restorations and decalcifications in the teeth under examination.
- Non-smokers.

The patients were randomly allocated to one of the two regimen groups. Following completion of active treatment, Group 1 (N = 15) received Vivera® retainers (Align Technology Inc., CA, USA) and Group 2 (N = 15) received Essix® C+ retainers (Raintree Essix, LA, USA). Following removal of the orthodontic appliances, PVS impressions were taken of each patient allocated to Group 1. The Vivera® retainers were made using the same technology as the Invisalign® aligners and according to the manufacturer's instructions. For each patient in Group 1, an Essix® retainer was manufactured to temporarily serve as a retainer until issue of the Vivera® retainers, in order to prevent potential post-treatment changes before the fabrication of the Vivera® appliance. Alginate impressions were taken on the same day as appliance removal for patients assigned to Group 2, and all retainers were of similar design and fabricated using 0.040 inch (1 mm) Essix® C+ sheet material. All of the Essix® retainers were produced by the same laboratory using working casts made from high-quality die stone.

Two retainers were manufactured for all patients in each group (1 and 2). The patients received only one appliance, as the duplicates served as controls and were stored away from sunlight at room temperature by the investigators.

Each patient was instructed to wear the retainers for 20 hours per day, except during oral hygiene procedures and eating or drinking beverages. The retainers were removed from the mouth twice a day and cleaned with a toothbrush under running water without using a disinfectant solution. During the retention phase, all patients were instructed to brush regularly with white fluoride toothpaste. Daily use of chlorhexidine mouth rinses was not allowed during the study to avoid pigmentation of the teeth. The Ethical Committee of the institution confirmed that the procedures detailed in the present clinical trial would be in compliance with the guidelines for good clinical practice. In addition, informed consent was received from all patients or their guardians.

A reflectance spectrophotometer, SpectroShade™ Micro (MHT Optic Research AG, Zurich, Switzerland; software version 2.20) was used to colour assess the materials. The SpectroShade™ has been found to provide precise measurements during longitudinal evaluations of tooth colour in vivo.[8] A standardised protocol of tooth preparation and retainer in vivo spectrophotometric colour evaluation was adopted for assessing the patients and all measurements were performed by the same operator in the same examination room with standardised lighting conditions. The spectrophotometric data from each tooth were recorded at three consecutive times (N = 3) by positioning, removing and repositioning the intraoral camera on the saliva-wetted labial surfaces of the retainers. The upper central incisors underwent

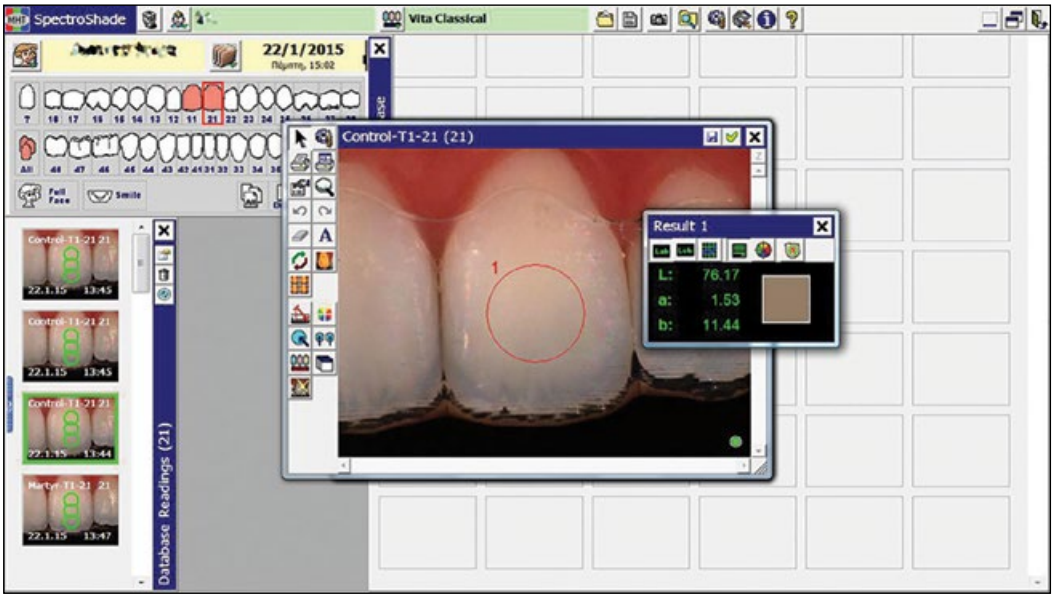


Figure 1. Spectrophotometric analysis of the labial surface of an incisor with a retainer on with the SpectroShade™ software.

spectrophotometric analysis on a standardised circular area in the middle third of their labial surfaces (Figure 1). The same measurements were also performed at each time point after insertion of the second aligner (control) and lastly with no retainer in place (tooth only).

All captured images were recorded at four time intervals:

T_0: Immediately after retainer insertion in the mouth.

T_1: After 15 days of intraoral use.

T_2: After one month of intraoral use.

T_3: After three months of intraoral use.

The spectrophotometric readings of each measurement were recorded and the colour of the measured specimen was identified in CIE L* a* b* colour parameters.[9] The coordinate L* is a measure of lightness and ranges from 0 (black) to 100 (white); a* and b* coordinates represent positions on a red/green and yellow/blue axis, respectively.[10] The CIE colour parameters were measured and averaged for each retainer material, and the resultant colour differences (ΔE) between the interval groups calculated according to the following equation:

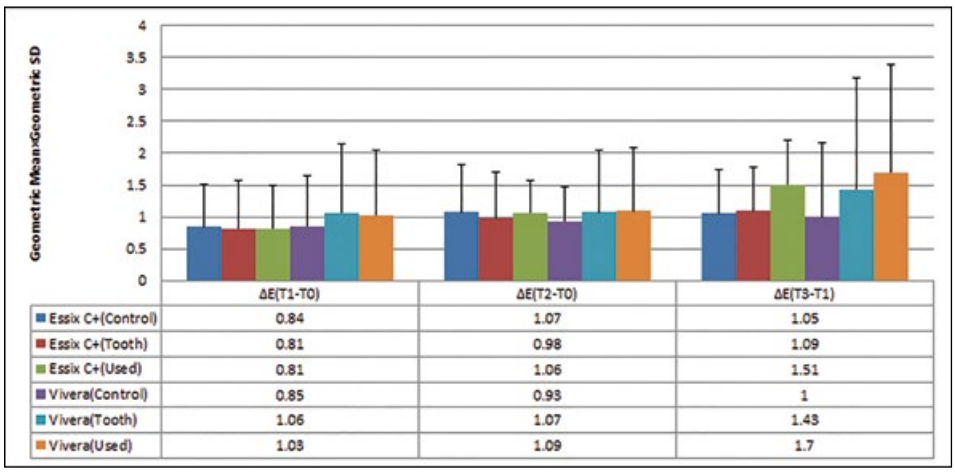
$$\Delta E = [(L^*i - L^*ii)^2 + (a^*i - a^*ii)^2 + (b^*i - b^*ii)^2]^{1/2}$$

where i and ii represent the colour measurements made at two different times.

The present study investigated the effect of the within-subject factors *Tooth* (two levels: upper right and left central incisor – 11 and 21, respectively), *Intervention* (Intervention; three levels: Used, Control and Tooth, for the used and unused retainers, and tooth without a retainer, respectively), *Time* (four levels: T_0-baseline, T_1, T_2 and T_3) and the between-subject factor *Group* (two levels: Vivera® and Essix® C+) on the colour of the teeth. A four-way ANOVA with repeated measures (univariate approach) model was applied for the statistical analysis of the L*, a* and b* chromatic parameters. In the case of rejection of the sphericity assumption, the Greenhouse-Geisser method for the epsilon correction was used. Pairwise comparisons were performed using the Bonferroni method.[11] The overall analysis was carried out with the IBM Statistics SPSS 21.0 software and the statistical significance was set at $p < 0.05$.

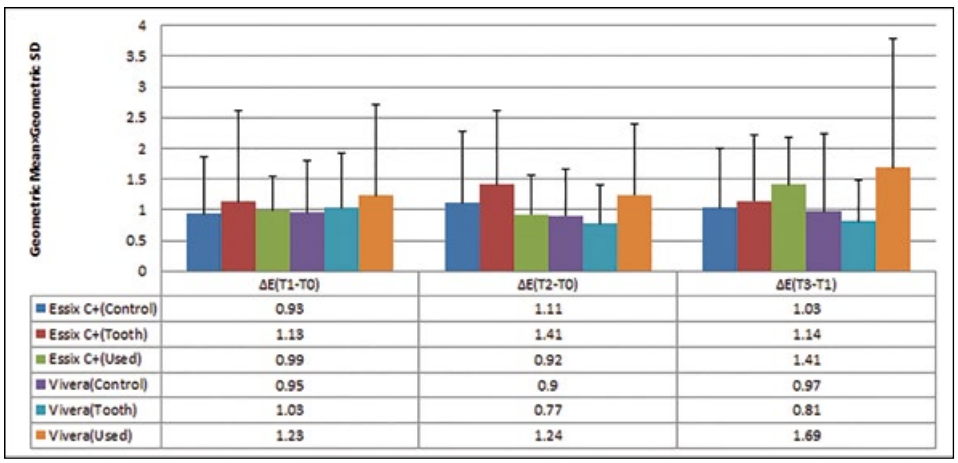
Method's error

To evaluate the intra-examiner reliability, the recordings of 15 patients' spectrophotometric data were repeated by the same operator one hour after the first measurement. All measurements were executed employing a repeated-measuring design (N = 3) by positioning, removing and repositioning the intraoral camera. The reproducibility of the measurements was estimated with Pearson's correlation coefficient[12] and the method error of the measurements was computed according to Dahlberg's formula.[13]



	ΔE(T1-T0)	ΔE(T2-T0)	ΔE(T3-T1)
Essix C+(Control)	0.84	1.07	1.05
Essix C+(Tooth)	0.81	0.98	1.09
Essix C+(Used)	0.81	1.06	1.51
Vivera(Control)	0.85	0.93	1
Vivera(Tooth)	1.06	1.07	1.43
Vivera(Used)	1.08	1.09	1.7

Figure 2. Geometric Mean × Geometric SD of the parameter ΔE for tooth 11.



	ΔE(T1-T0)	ΔE(T2-T0)	ΔE(T3-T1)
Essix C+(Control)	0.93	1.11	1.03
Essix C+(Tooth)	1.13	1.41	1.14
Essix C+(Used)	0.99	0.92	1.41
Vivera(Control)	0.95	0.9	0.97
Vivera(Tooth)	1.03	0.77	0.81
Vivera(Used)	1.23	1.24	1.69

Figure 3. Geometric Mean × Geometric SD of the parameter ΔE for tooth 21.

Results

Overall, of the 30 patients originally enrolled, 29 completed participation in the study as there was one dropout. Group 1 (Vivera®) consisted of 15 patients (12 females, mean and SD age 18.9 ± 3.9 y; three males, mean and SD age 16.8 ± 2.2 y), while Group 2 (Essix® C+) consisted of 14 patients (10 females, mean and SD age 15.5 ± 2.7 y; four males, mean and SD age 16.9 ± 0.6 y). Age was recorded at the end of active orthodontic therapy.

Only the interaction between *Time* and *Group* was found to be statistically significant ($p = 0.010$) for the L* parameter. No statistically significant difference was found between Vivera® and Essix® C+ materials at any of the *Time* points.

The main effect of *Group* on the a* parameter was found to be statistically significant ($p = 0.017$), as well as the interaction between *Time* and *Tooth* ($p = 0.045$). Essix® C+ showed a statistically significant higher mean value than Vivera® ($p = 0.017$). No statistically significant differences were found between teeth examined at each time point ($p > 0.05$).

The following interactions were found to be statistically significant relative to the b* parameter: between *Tooth* and *Group* ($p = 0.008$), the main effect of *Intervention* ($p < 0.001$), the interaction between *Intervention* and *Group* ($p = 0.007$) and the interaction of *Intervention* with *Time* ($p < 0.001$).

No difference was observed between groups within any level of *Tooth* or any combination of the factors *Intervention* and *Time*. For the Vivera® group, the level Used for factor *Intervention* demonstrated a greater mean value than the Control group ($p < 0.001$) at T_3. For the Essix® C+ group at all levels of factor *Intervention*, no difference was observed between time points ($p > 0.05$).

Descriptive statistics for ΔE are shown in Figures 2 and 3. Statistically significant results were found

Table I. Pairwise comparisons between the levels of the factor *Time* within the levels of the factor *Intervention*, with the Bonferroni method (Mean and SE are given after the inverse transformation with the function e^x).

Intervention	(I) *Time*	(J) *Time*	Ratio of Means (I/J)	*SE*	*p*-value
Used	T_{1-0}	T_{2-0}	0.94	1.09	1.00
		T_{3-0}	0.64	1.11	0.001**
	T_{2-0}	T_{1-0}	1.07	1.09	1.00
		T_{3-0}	0.68	1.08	<0.001***
	T_{3-0}	T_{1-0}	1.56	1.11	0.001**
		T_{2-0}	1.47	1.08	<0.001***
Control	T_{1-0}	T_{2-0}	0.89	1.10	0.752
		T_{3-0}	0.88	1.12	0.771
	T_{2-0}	T_{1-0}	1.12	1.10	0.752
		T_{3-0}	0.99	1.11	1.00
	T_{3-0}	T_{1-0}	1.13	1.12	0.771
		T_{2-0}	1.01	1.11	1.00
Tooth	T_{1-0}	T_{2-0}	0.97	1.10	1.00
		T_{3-0}	0.91	1.12	1.00
	T_{2-0}	T_{1-0}	1.03	1.10	1.00
		T_{3-0}	0.94	1.10	1.00
	T_{3-0}	T_{1-0}	1.09	1.12	1.00
		T_{2-0}	1.06	1.10	1.00

**: $p < 0.01$, ***: $p < 0.001$

for ΔE related to: *Intervention* (p = 0.017), *Time* (p = 0.002), the interaction between the factors *Tooth*, *Intervention* and *Group* (p = 0.045), the interaction between *Tooth* and *Time* (p = 0.024) and the interaction between the factors *Intervention* and *Time* (p = 0.033). According to partial eta squared values, *Time* was found to be the most important factor.

In relation to the *Tooth* by *Time* interaction, colour changes from T_0 to T_1, T_0 to T_2 and T_0 to T_3 showed no statistically significant differences between tooth 11 and 21.

In relation to the *Intervention* by *Time* interaction, colour changes between T_3 and T_0 at level Used were 1.55 times higher than those at level Control (p = 0.002), and 1.44 times higher than those at level Tooth (p = 0.004). Also, at level Used for factor *Intervention*, colour changes between T_3 and T_0 were 1.56 times higher than those between T_1 and T_0 and 1.47 higher than those between T_2 and T_0 ($p < 0.001$) (Table I).

No significant differences in colour change were observed between Vivera® and Essix® C+ material groups in regard to the interaction of *Group* by *Intervention* by *Tooth*, within any combination of the levels of factors *Intervention* and *Tooth*.

Method's error

The Pearson's r correlation coefficient for the L* parameter was 0.988, for the b* colour parameter was 0.991, while the a* parameter was found equal to 0.957. Dahlberg's method error formula gave a value equal to 0.23 for the L* parameter, 0.15 for the a* parameter and 0.27 for the b* parameter. Mean ΔE was equal to 0.4 ± 0.3 (from 0.12 to 1.3), while the value 1.3 (greater than 1) was observed in one case (7%). Based on these results, the investigator's reliability was judged to be acceptable and the method error insignificant.

Discussion

No statistically significant difference was found in the chromatic parameter L* between Vivera® and Essix® C+ material at any time point. However for the Essix® C+ group, measurements of L* showed greater mean value at T_3 than at T_2 or T_1, which implies that the combined colour of the retainers and the tooth became less dark by T_3.

Essix® C+ showed a statistically significant higher mean value for chromatic parameter a* than Vivera®,

meaning that the Essix® C+ group exhibited a colour closer to red at all time points.

No difference was found between Vivera® and Essix® C+ groups for chromatic parameter b*. In the Vivera® group, Used retainers showed a higher mean value than Control retainers only at T_3. The increase in b* values indicates a shift in the colour of Vivera® retainers toward yellow. The measured teeth in the same group showed no difference between any of the time points, indicating stability in their colour. No difference was observed in the Essix® C+ group between Used retainers, Control retainers and Teeth-only measurements at any time point.

No significant differences in colour change were observed between Vivera® and Essix® C+ groups for the ΔE parameter for any combination of *Intervention* type and *Tooth*. This means that the two different types of retainers exhibited similar colour stability after a period of three months oral use. There were no statistically significant differences in ΔE between tooth 11 and 21 at all time points.

Used retainer colour changes between T_3 and T_0 were 1.55 times higher than those of Control retainers and 1.44 times higher than those of teeth alone. Also, the Used retainer colour changes between T_3 and T_0 were 1.56 times higher than those between T_1 and T_0 and 1.47 higher than those between T_2 and T_0. This means that the Used retainers exhibited greater colour changes than the Control retainers or Teeth-only and that these changes increased as the duration of their use increased.

All ΔE values observed in the present study were considered clinically acceptable (ΔE < 3.7). However, prolonged use of the retainers could possibly cause clinically significant changes in their colour. In this investigation, the retainer material was evaluated for three months, as this period is a commonly proposed time for full-time wear after debond,[3] after which retainer staining is potentially less important for patients, as they are worn at night-time only.

The discolouration of polymeric materials can be attributable to a wide range of causes. One possible factor is the extrinsic discolouration produced by the superficial absorption or adsorption of colour pigmentation from food dyes, coloured mouth rinses, plaque or the tinted components produced by the chromogenic bacterial plaque or from chemical alterations in pellicle components.[15-17] Another possible cause is the discolouration of the surface from absorption or superficial penetration of staining agents passing through the oral cavity after chemical degradation of the material surface or discolouration of the outer layers produced by superficial diffusion of hydrophilic colourings.[18] Lastly, internal discolouration derived from incomplete polymerisation and endogenous irreversible discolouration caused by changes in the chemical structure of the material are also possible.[18]

The current study tested retainers fabricated from two different polymer materials, namely polypropylene (Essix® C+) and polyurethane (Vivera®), respectively. To the best of current knowledge, there is no published information on colour changes associated with polypropylene retainers. However, considerable change has been reported in the morphology of polyurethane aligners, after two weeks of use, caused by the functions of speech, swallowing and bruxism, which alter the superficial and structural characteristics of the retainer material,[4,19] thus making the aligners more opaque.[4] External discolouration could be a result of time, temperature and pH when retainers are worn during the drinking of coffee, wine, tea, acidic soft drinks, fruit juices or other liquids. It has been shown that coffee, tea and, to a lesser extent, red wine produce visible changes in the colour of a polyurethane retainer.[7] A previous in vitro study has also shown that Invisalign® aligners were significantly stained after a 12-hour immersion in coffee, although red wine and tea failed to cause significant changes over the same time period.[20] However, an additional in vitro study failed to show statistically significant changes in Invisalign® aligners after two two-week immersion cycles in artificial saliva with brown and yellow food colouring.[21] Moreover, phenomena such as adsorption of proteinaceous substances and local calcification of inactive points have been shown to occur in the surface of the retainers, and thus could be factors influencing their colour.[4,19]

The aesthetic characteristics of thermoplastic retainers can be influenced by the underlying tooth colour. The colour of natural tooth enamel has been shown to change in a variety of ways after fixed orthodontic treatment,[22-28] with the colour change being shown to be affected by many factors including the type of adhesive materials and debonding procedures used.[24-29] Enamel colour has also been shown to change during the first retention year, with the majority of changes exhibited during the first three months.[30]

The effect of random and systematic errors on the in vivo quantitative assessment of the retainer and tooth colour and, subsequently, the precision of intraoral spectrophotometric measurements comprise limitations of this clinical trial. The SpectroShade™ equipment has been found to provide precise measurements during longitudinal evaluation of tooth colour in vivo[8] and is considered a reliable device[31-37] with reported 96.9% reliability and 80.2% accuracy.[32] Systematic errors are intrinsic to all instruments and may result from calibration techniques, fluorescence, instrument metamerism, and variations in measurement geometry.[34] The degree of uncertainty during the measuring process is related primarily to random errors. The minimisation of random errors was accomplished in this trial by multiple measuring and averaging, along with improved control of the methodological and environmental factors.

Knowledge of the effects of the staining susceptibility of the surface of the thermoplastic retainer could guide clinicians regarding the choice of the material used for their patients, so that better long-term retainer maintenance and colour stability are achieved. The present findings suggest that polyurethane and polypropylene retainers exhibit similar optical behaviour during a three-month period of oral wear. Further research on different materials or different modes of retainer use would be necessary to study the physical and optical properties of thermoplastic material when retainers are subjected to the hostile conditions of the oral cavity for longer periods of use.

Conclusion

The present study indicates that the Used retainers exhibited greater colour change than the Control or Teeth-only retainers and these changes increased commensurate with wear time. Vivera® and Essix® C+ retainers exhibited similar colour stability after three months of oral use, as no significant differences in colour change were observed between the two retainer types. All retainer colour differences observed in vivo after a three-month post-treatment period were considered clinically acceptable ($\Delta E < 3.7$), although prolonged use of the retainers could possibly cause clinically significant deterioration in colour. The null hypothesis for this study was rejected since the CIE colour parameters L*, a*, and b* of retainers showed statistically significant differences before and after intraoral exposure.

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