In vitro efficacy and risk for adverse effects of light-assisted tooth bleaching

Ellen M. Bruzell,*[a] Bjørn Johnsen,[b] Tommy Nakken Aalerud,[b] Jon E. Dahl[a] and Terje Christensen[b]

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The use of optical radiation in the so-called light-assisted tooth bleaching procedures has been suggested to enhance the oxidizing effect of the bleaching agent, hydrogen peroxide. Documentation is scarce on the potential adverse effects of bleaching products and on optical exposure risks to eyes and skin. The efficacy of seven bleaching products with or without simultaneous use of seven different bleaching lamps was investigated using extracted human teeth. The bleaching effect was determined immediately after treatment and one week later. Tooth surfaces were examined for adverse alterations after bleaching using a scanning electron microscope. Source characteristics of eight lamps intended for tooth bleaching were determined. International guidelines on optical radiation were used to assess eye and skin exposure hazards due to UV and visible light emission from the lamps. Inspection of teeth one week after bleaching showed no difference in efficacy between teeth bleached with or without irradiation for any of the products. Scratches, probably from the cleaning procedure were frequently seen on bleached enamel irrespective of irradiation. Maximum permissible exposure time (t_{max}) and threshold limit values were exceeded for about half the bleaching lamps investigated. One lamp exceeded t_{max} even for reflected blue light within the treatment time. This lamp also exceeded t_{max} values for UV exposure. The lamps were classified as "low risk" and as borderline to "moderate risk" according to a relevant lamp standard.

Introduction

Tooth whitening has become one of the most popular aesthetic treatments of teeth.[1] The first described external tooth bleaching procedures were a self-administered technique using 10% carbamide peroxide in a tray[2] and a faster, in-office technique utilizing 37% hydrogen peroxide (H_2O_2) originally assisted by a heat source.[3] Several manufacturers have later made variations on these methods commercially available. H_2O_2 may be applied directly on the teeth as an oxidizing agent. The reactive oxygen species formed in the decomposition reaction can react with chromophores in the tooth enamel and dentin and split them into smaller, less coloured and more diffusible molecules.[4] In-office treatment combined with a light source is suggested to improve the oxidizing effect.[5] More recent publications indicate that the benefit of the additional use of light is limited.[6]

Among local adverse effects associated with tooth bleaching is alteration of enamel surface.[4] This change can be expressed as increased roughness, decreased microhardness and changes in morphology of dental enamel surfaces.[7] It has been shown that bleaching over even short periods of time caused morphological alterations of the enamel surface.[8]

Medical or aesthetic treatment with strong optical radiation sources may pose risks to the operator and the person being subject to the treatment.[9-12] Optical sources such as light emitting diodes (LED), halogen lamps, plasma arc lamps and lasers are most commonly used for tooth bleaching. However, information on adverse effects related to bleaching lamps is scarce. Therefore, it is valuable to assess whether blue light and ultraviolet (UV) radiation emitted from bleaching lamps exceed recommended exposure limits for occupational and general exposure related to eye and skin.

The aims of this study were threefold: to evaluate if the additional irradiation during tooth bleaching influenced the outcome of the procedure, to examine the surface of the enamel for adverse alterations after bleaching with or without irradiation, and to assess potential eye and skin hazards from the exposure to irradiation.

Materials and methods

1.0 Efficacy of light-assisted bleaching

1.1 Teeth. Intact human molars and premolars were received in the laboratory no later than 14 days after extraction. The teeth were kept in fluoride solution (0.5 mg ml^{-1}, Nycomed Pharma A/S, Norway) from the time of extraction until use (at 3–4 °C) and for one week post-bleaching (at 37 °C) prior to the final shade determination. Otherwise, distilled water was used when the bleaching procedure required the teeth to be kept moist. The teeth were polished prior to bleaching using polish paste in a rubber cup and a low-speed hand-piece. Ten to twenty teeth were investigated per product (including controls).

1.2 Bleaching gels and light sources. Seven different bleaching systems (bleaching gels combined with light sources) were investigated (Table 1). All systems that were commercially available on the Scandinavian and United States' markets in 2005 were included in the study.

1.3 Bleaching procedure. All teeth were sectioned buccolingually to obtain two separate halves of each tooth. The buccal

[a]*Nordic Institute of Dental Materials (NIOM), NO-1305, Haslum, Norway*
[b]*Norwegian Radiation Protection Authority (NRPA), NO-1332, Østerås, Norway. E-mail: ebr@niom.no*

Table 1 Bleaching products and lamps (names in bold appear in figure texts)

Bleaching product name (H_2O_2 conc. per manufacturer)	Was the recommended (by manufacturer) lamp used?	Bleaching product manufacturer	Lamp name	Lamp manufacturer
Beyond Whitening Accelerator (35%)	Yes	Beyond Technology Corp., Santa Clara, CA, USA	**Beyond** Whitening Accelerator	Beyond Technology Corp., Santa Clara, CA, USA
Gentle Bright Light-Activated Whitener[a] (Not given)	No (curing lamp with bleaching mode was selected)	Lumalite, Spring Valley, CA, USA	**VCL Complete**	sds Kerr, Danbury, CT, USA
Luma White (3%)	Yes	Lumalite, Spring Valley, CA, USA	**Luma Cool Whitening** System	Lumalite, Spring Valley, CA, USA
Pola Office Advanced Tooth Whitening System[b] (35%)	All lamps designed for the purpose claimed to be effective	SDI Ltd., Bayswater, Victoria, Australia	**Swiss Master Light**	EMS, Nyon, Switzerland
Rembrandt Lightning Plus (35%)	Yes	DenMat, Santa Maria, CA, USA	**Sapphire** with Sapphire Crystal	DenMat, Santa Maria, CA, USA
White Smile Forever White (17%[c])	Yes	CT, Inc., Kearns, UT, USA	**Remecure CL-15** Curing & Whitening Device	Remedent NV, Deurle, Belgium
Zoom! Chairside Whitening Gel (16%)	Yes	Discus Dental Inc., Culver City, CA, USA	**Zoom!**	Discus Dental Inc., Culver City, CA, USA
—[d]			**BriteSmile**[d]	BriteSmile Inc, Boca Raton, FL, USA

[a] The bleaching gel was randomly chosen among available bleaching systems in accordance with the VCL lamp manufacturer's claim that any light-activated bleaching product could be used with the lamp. [b] The bleaching gel was chosen to be used with the light source Swiss Master Light since the lamp manufacturer offered a free sample of the bleaching product when the lamp was purchased. Hence, there was a strong indication that this particular lamp and bleaching product would be combined in the clinic. [c] Choice of H_2O_2 concentration; 17% was recommended. [d] Bleaching efficacy was not investigated for BriteSmile. Lamp was measured in a beauty clinic.

surface of one half was bleached according to the recommendation of the manufacturer and the other half served as unexposed control. For each bleaching system, the buccal halves of teeth 1–5 and 6–10 were exposed to bleaching gel and irradiation and to bleaching gel without irradiation, respectively. The Vita Shade Guide (Lumin® Vacuum-Farbskala, Vita Zahnfabrik H. Rauter GmbH & Co., Bad Säckingen, Germany) was used to determine the shade before, immediately after and one week after treatment. The sequence of the shade names according to degree of brightness is the following: B1 (brightest), A1, B2, D2, A2, C1, C2, D4, A3, D3, B3, A3.5, B4, C3, A4 and C4 (least bright). The shades were given a score graded by brightness so that score 1 corresponded to B1, score 2 corresponded to A1, *etc.*, and finally score 16 corresponded to C4. The numerical values were used to assess changes in brightness (also called degree of lightening). The tooth shade assessments were performed in a light box (Color-Chex™, Atlas Electric Devices Company, Chicago, IL, USA) with a uniform background and surroundings with respect to light. The same two persons, experienced in shade assessment, determined the shades throughout the study. Some observed teeth shades did not correlate with any of the existing shades on the Vita Shade Guide. In such cases the arithmetic mean score was used corresponding to the scores of the two most similar shades. Mean values of shade scores that were not whole numbers were rounded off to the closest whole number.

2.0 Evaluation of tooth surface

After the final shade evaluation, the specimens were placed on the bench for 1 week for dehydration, mounted on retainers and coated with 20 nm layer of gold–palladium alloy (Sputtering device: SCD 050 Sputtercoater, Balzers, Lichtenstein). The specimens were examined by scanning electron microscopy (SEM) (XL 30; Philips, Eindhoven, the Netherlands) at 10.0 kV.

3.0 Radiation risk assessment

3.1 Laboratory measurement of source characteristics. Emission spectra in the wavelength band 290–700 nm at 30 cm distance were measured for seven lamps by a double monochromator spectroradiometer (model DTM300, Bentham Instruments Ltd., Reading, UK). An optical light guide, fitted with a 100 mm diameter integrating sphere, optionally a 10 mm diameter cosine corrected flat diffuser served as input optics for measurements of spectral flux and irradiance. The instrument utilized a bi-alkaline photomultiplier tube and a silicon photodiode for optimum spectral responsivity in the UV and near infra-red. Non-linearity in detector responses that would be induced by powerful lamps were avoided by the use of a computer controlled neutral density filter wheel. Wavelength calibrations were made against emission lines from a low-pressure mercury lamp and a neon lamp. Irradiance calibrations for the respective input optics were made with 1000 W quartz-tungsten-halogen lamps, traceable to the National Institute of Standards and Technology (Gaithersburg, MD, USA) *via* the Swedish Testing and Research Institute (Borås, Sweden). All lamps were measured once, with the exception of Zoom (for lamp details, see Table 1) which was measured three times. Spectral data for the curing lamp with bleaching mode VCL Complete were obtained previously (Swedish Testing and Research Institute).

3.2 In-clinic measurements by broadband radiometer. Irradiance from three lamps: Remecure CL-15 Curing & Whitening Device, Zoom and BriteSmile were measured with a portable broadband radiometer (Solar Light Inc., Philadelphia, PA, USA; model PMA2100) with the following radiometer heads: PMA2120 UV-B (UV-safety, *i.e.* responsivity function mimicking the UV hazard function[13,14]), PMA2110 UVA and PMA2121 Blue light safety (responsivity function mimicking the blue-light hazard function[13,14]). Measurements of direct irradiation were performed in various distances from the source. Two different BriteSmile lamps were measured. The radiometer heads were calibrated by the manufacturer, and the calibration was checked against spectroradiometer measurements. Blue light safety detector measurements that exceeded 2.5 mW cm^{-2} were uncertain as the saturation limit was close to 2.6 mW cm^{-2}.

3.3 Derived quantities used for calculations of maximum permissible exposure duration (t_{max}) and assessment of threshold limit values (TLVs). To determine the radiance, L, from the measured irradiance, E_m, emitted from the source to the target in a certain distance, the following relationship was used[15]:

$$E_m = L \times \Omega_{d\text{-}s} = L \times \pi \times \sin^2\theta_{d\text{-}s} \quad (1)$$

where $\Omega_{d\text{-}s}$ is the projected solid angle subtended by the source as seen from the detector (target) and $\theta_{d\text{-}s}$ is the corresponding planar half-angle. All equations containing solid angle were based on the half-angle of the angular subtence. This angle was defined on the basis of the source-target distance and the radius of a circular area equivalent to the area of the irradiation spot.

The radiance can be expressed as the radiant flux emitted from the source, Φ_{em}, per source area, A_s, and projection of the source solid angle, Ω_s. Furthermore, the radiant exitance of a source, M_s, is the ratio between the radiant flux emitted from the source and the source area:

$$L = \Phi_{em}/(A_s \times \Omega_s) = M_s/\Omega_s \quad (2)$$

3.4 Estimation of t_{max}, assessment of TLVs and lamp safety classification.

3.4.1 Choice of physical parameters. Estimations of lamp radiometric values compared with limit values from direct and reflected radiation were made for distances up to 35 cm between the source or reflective surface and the target. The areas of a single tooth and a set of twelve teeth were approximated to 1 cm^2 and 8 cm^2, respectively. Reflectance was chosen to be 0.3.[9,16] The tooth/teeth areas were assumed to be Lambertian sources, *i.e.* isotropically scattering.

3.4.2 t_{max} for direct blue light (laboratory and clinic). A weighted (by the blue-light hazard function, $B(\lambda)$[17]) dose limit of 100 J per (cm^{2}xsr) per day is set for acute and chronic eye (retinal) blue light exposure. This dose limit pertains to artificial sources for workers[17,18] and the general public[17] in any 8 hour workday and exposure duration <10^4 s.[17,18]

$$t_{max} = [100\ \mathrm{J/(cm^2 \times sr)}]/L_{blue} \quad (3)$$

where L_{blue} is the source radiance, L_λ, ($400 < \lambda < 700$ nm) (eqn (1)) weighted against $B(\lambda)$.

Radiance estimation for computation of t_{max} for reflected blue light (laboratory). Using the expression for Φ_{em} and L in eqn (2), the radiance reflected from a tooth area can be written as:

$$L_{tooth} = \rho \times M_s/\pi \quad (4)$$

($\sin^2\theta = 1$ due to assumption of isotropic scattering conditions) where ρ is the reflectance.

Substituting for M_s yields an expression for source radiance reflected from the tooth:

$$L_{tooth} = (\rho \times L \times A_s \times \Omega_{s\text{-}w})/(\pi \times A_s) \quad (5)$$

where $\Omega_{s\text{-}w}$ is the solid angle between the source and an irradiated area (*e.g.* a wall) projected in the source plane. Further substituting for the solid angle as in eqn (1):

$$L_{tooth} = \rho \times L \times \sin^2\theta_{s\text{-}w} \quad (6)$$

where $\theta_{s\text{-}w}$ is the corresponding planar half-angle of $\Omega_{s\text{-}w}$.

To obtain t_{max} for reflected blue light measured by the spectroradiometer, L_{tooth} was substituted by L_{blue} in eqn (3).

Radiance estimation for computation of t_{max} for reflected blue light (clinic). Irradiance measurements in the clinic were achieved by the broadband radiometer using the blue light safety radiometer at 30–35 cm distance (source dependent distance) from the lamp. The radiance was calculated using eqn (1). Substituting the expression for L from eqn (1) by L in eqn (6) and setting reflectance, ρ, to 0.3 yield the expression for L_{tooth} below based on measured irradiance. Eqn (3) can then be solved for t_{max}:

$$L_{tooth} = 0.3 \times [E_m/(\pi \times \sin^2\theta_{d\text{-}s})] \times \sin^2\theta_{s\text{-}w} \quad (7)$$

3.4.3 t_{max} and TLVs for UV radiation. A weighted (by an action spectrum) dose limit of 0.0030 J cm^{-2} is set for eye and skin UV exposure (180–400 nm) from artificial sources for workers[13,14] and the general public.[14] This dose applies to exposure durations up to 8 h per day.[14] Thus, it follows that:

$$t_{max,UV} = [0.0030\ \mathrm{J\ cm^{-2}}]/E_{eff} \quad (8)$$

where E_{eff} is the effective irradiance *i.e.* the source spectral irradiance weighted by the UV-hazard function, $S(\lambda)$.[13]

Furthermore, for eye exposure a maximum unweighted dose of 1 J cm^{-2} or source irradiance of 1 mW cm^{-2} (TLVs) is set in the wavelength range 315–400 nm for exposure durations of ≤1000 s or ≥1000 s, respectively.[13]

t_{max} for direct UV radiation. Irradiance values to be $S(\lambda)$-weighted and substituted in eqn (8) were obtained from measurements with the spectroradiometer in the laboratory. In the clinics, weighted and unweighted UVA irradiance values were obtained directly by the UV-hazard detector and the UVA-detector of the portable radiometer, respectively. Weighted irradiance (weighted radiant exitance at a very close distance) was used for estimations of t_{max} at 5–35 cm distance and unweighted irradiance (or unweighted radiant exitance) for estimations of TLVs.

t_{max} for reflected UV radiation. Irradiance of reflected UV from a source (the teeth of a client) to the eye of a lamp operator, E_e, was calculated from values of reflected UV radiance, $L_{UV,ref}$ (ρ = 0.3):

$$E_e = \Phi_{tooth}/A_e = (L_{UV,ref} \times \Omega_{e\text{-}t}) \quad (9)$$

where Φ_{tooth} is the flux scattered/reflected from the teeth and $\Omega_{e\text{-}t}$ is the solid angle subtended by the teeth as seen from the eye. Applying the definition of a solid angle, the following equation was obtained for E_e:

$$E_e = L_{UV,ref} \times \pi \times \sin^2\theta_{e\text{-}t} \quad (10)$$

where $\theta_{e\text{-}t}$ is the corresponding planar half-angle of $\Omega_{e\text{-}t}$. To obtain t_{max} for reflected UV, E_e was substituted by E_{eff} in eqn (8).

3.5 Lamp safety classification. Based on the irradiance and radiance obtained by the methods outlined above, the lamps were classified according to CIE's Standard on photobiological safety of lamps.[19] According to ref. 19, hazard values shall be reported at 200 mm. The measured emission values were recalculated to obtain values at this specified distance. The standard classifies potential risk into four groups: Exempt group, Risk Group 1 (Low-Risk), Risk Group 2 (Moderate-Risk) and Risk Group 3 (High-Risk). Values of the following hazard functions, representing emission limits in the standard, were used to classify each lamp into risk groups: actinic UV hazard (E_s), near-UV hazard (E_{UVA}) and retinal blue-light hazard (L_A).

4.0 Statistics and uncertainty assessment

4.1 Bleaching efficacy. Statistical computations were carried out using SPSS for Windows, version 15.0. Comparisons of groups of bleach/light-treated teeth to control groups were performed by the non-parametric method, Wilcoxon Signed Ranks Test ($p \leq 0.05$). A 95% confidence interval was estimated.

4.2 Lamp measurements. Bentham spectroradiometer and Solar Light broadband radiometer irradiance measurements uncertainties were estimated to ±10% and ±20% (2-σ confidence interval), respectively. Uncertainties in solid angle measurements were estimated to be within ±20%, resulting in ±22% and ±28% total uncertainty in radiance measurements for the spectroradiometer and broadband radiometer, respectively.

Results

1.0 Efficacy assessment of light-assisted bleaching

1.1 Immediate post-treatment. Immediate post-treatment change in degree of lightening for the seven bleaching systems with and without simultaneous irradiation is shown in Fig. 1. Bleaching combined with irradiation did not statistically significantly increase the degree of lightening compared with bleaching without irradiation, except for Zoom.[20]

1.2 One week post-treatment. Degree of lightening of exposed and unexposed teeth was compared for the second time after storage in fluoride solution for 1 week. Bleaching with irradiation did not result in significant differences in degree of lightening compared with treatment without irradiation for any of the bleaching products (Fig. 2).[20]

2.0 Evaluation of tooth surface

The enamel surface of control (unbleached) teeth varied from smooth to uneven with occasionally observed perichymata (Fig. 3). On bleached teeth perichymata were more often observed (not shown) and the surface often appeared "scratched" (Fig. 4). There were neither marked differences among the bleaching products nor between the procedures with or without the use of irradiation.

3.0 Radiation risk assessment

3.1 Laboratory measurement of source characteristics. The radiant exitance values (distance ≈ 0) estimated from irradiance measurements at 30 cm distance in the wavelength interval 290–700 nm are presented in Table 2. Radiant exitance values were multiplied by each lamp's recommended exposure time to obtain the approximate clinical light doses. The doses intended to improve lightening effect by bleaching varied by a factor ≈ 3×10^3 J cm^{-2} (Table 2).

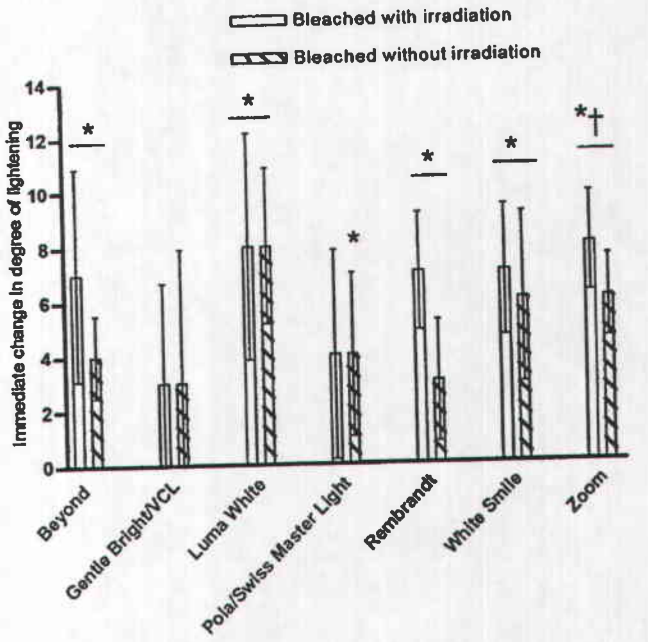

Fig. 1 Mean and 95% confidence interval of immediate changes in degree of lightening of extracted teeth after bleaching procedure with and without irradiation. †: Statistically significant difference between teeth bleached with and without irradiation, $p < 0.05$. *: Statistically significant difference between bleached and non-bleached teeth, $p < 0.05$. The horizontal lines underlining the symbols (*, †) denote that significance was obtained in both the irradiated and the non-irradiated group. $n = 5$ (except Gentle Bright/VCL: $n = 4$; Rembrandt and Zoom: $n = 10$).[20]

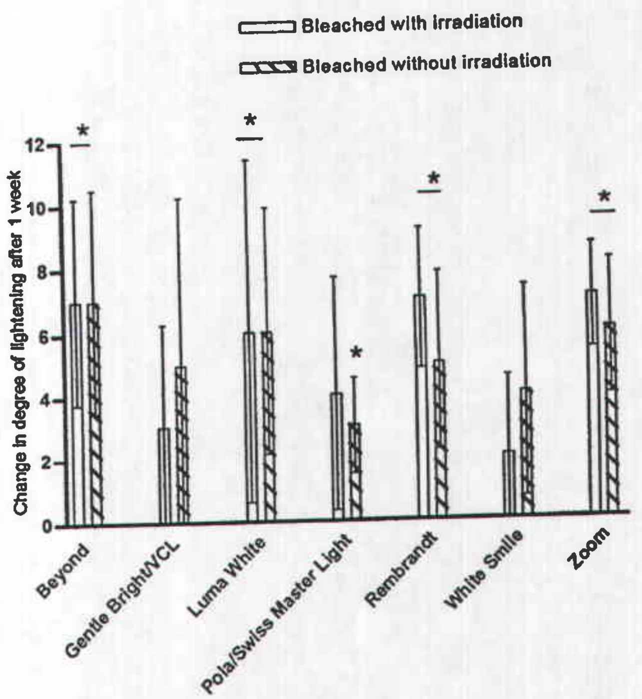

Fig. 2 Mean and 95% confidence interval of 1 week post-treatment changes in degree of lightening of extracted teeth after bleaching procedure with and without irradiation. * and n: see Fig. 1.[20]

Table 2 Spectral data and physical treatment parameters of the bleaching lamps investigated

Lamp name	Lamp type	Approximate wavelength interval^{a}/nm	Radiant exitance^{b}/mW cm^{-2}	Light dose^{c}/J cm^{-2} per treatment	Distance between teeth and light guide/mm
Beyond Whitening Accelerator	Halogen	390–740	169	243	10
BriteSmile	—^{d}	Visible light. No UV^{d}	44^{e}	158	—^{d}
Luma Cool Whitening System	LED	410–750	16	23	10
Remecure CL-15 Curing & Whitening Device	Plasma arc	390–500	89	320	2
Sapphire with Sapphire Crystal	Plasma arc	390–530	64	230	12
Swiss Master Light	Halogen	390–550	77	0.9	5
VCL Complete	Halogen	370–510	1087	33	2
Zoom!	Plasma arc	350–650	686	2469	38

^{a} Wavelength interval where irradiance values are within 1% of the lamps' maximum spectral irradiance value. ^{b} Radiant exitance was estimated based on measured irradiance (wavelength interval: 290–700 nm). ^{c} The light dose was estimated based on manufacturers' given treatment duration. The distance between teeth and light guide was measured based on manufacturers' advice or constricted by the retractor when such device was used. ^{d} Data not available. ^{e} Lamp was measured by broadband radiometer in a beauty clinic.

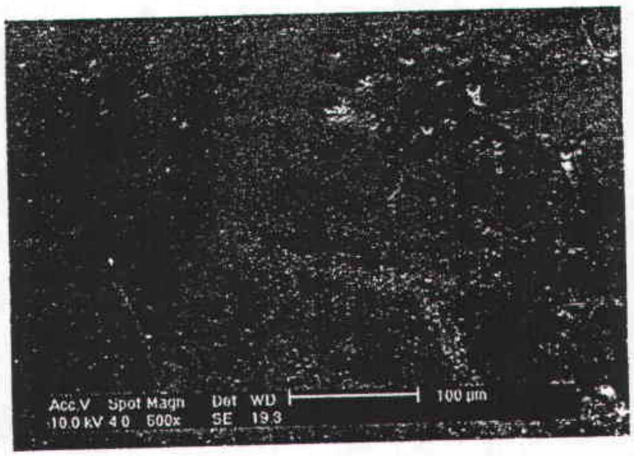

Fig. 3 SEM image of enamel surface of control (unbleached) tooth.

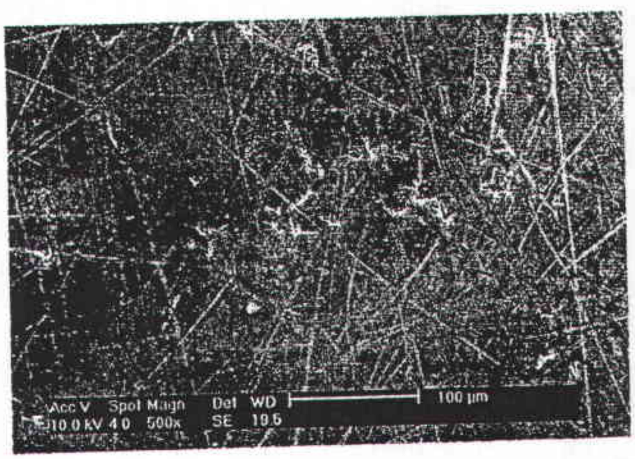

Fig. 4 SEM image demonstrating "scratched" surface of bleached tooth 2 weeks post-treatment.

3.2 t_{max} for direct blue light (clients' exposure). t_{max} values for retinal exposure to direct blue light for seven lamps are shown in Table 3. Remecure, Sapphire, Zoom and BriteSmile emitted radiation which exceeded the exposure limit before the recommended treatment time had elapsed (Tables 2, 3). Of these lamps, t_{max} values were in the order of one-tenth (Zoom) to two-thirds (Sapphire) of the treatment duration. Furthermore, treatment time was equal to or longer than t_{max} for VCL Complete curing/bleaching lamp if four or more teeth, respectively, were bleached in succession, but not after treatment of a single tooth.

3.3 t_{max} and excess of TLVs for direct UV radiation (clients' exposure). t_{max} for the Zoom lamp only was shorter than treatment duration (Tables 2, 4). This value was obtained when UV exposure to skin and eye (cornea) was weighted with the $S(\lambda)$-function for distances close to 0 cm (both radiometers) and at 5 cm (only broadband radiometer) (Table 4). When dose limits were assessed, based on unweighted UVA, TLVs for direct eye exposure in short distances (<5 cm) were exceeded for Remecure, Sapphire, VCL Complete and Zoom. Furthermore, for Zoom TLVs were exceeded in a distance up to 30 cm.

3.4 Number of treatments before t_{max} was reached for reflected radiation (operators' exposure). Reflected blue light from Remecure, Sapphire, Zoom and BriteSmile gave t_{max} values shorter than an 8 hour workday period in a distance of 30 cm. Expressed as the number of treatments before t_{max} was reached, values varied from one to eight treatments for the above-mentioned lamps (Table 5). t_{max} values for reflected UV radiation in a distance of 30 cm between a reflecting surface and the eyes of an operator were longer than an 8 hour workday for all the lamps in this study (data not shown).

3.5 Lamp hazard classification. The bleaching lamps in the study were classified into the following risk categories: All lamps met the requirements for Risk Group 1 (Low-Risk) when emission of blue light was assessed (Table 6). For this radiation hazard VCL Complete and Zoom were classified as borderline between Risk Group 1 and Risk Group 2 (Moderate-Risk). These two lamps also met the requirements of Risk Group 1 for both actinic and near-UV hazards. The UV radiation emitted by Zoom classified the lamp as borderline between Risk Groups 1 and 2 (Table 6). Thus, all lamps could be classified as Risk Group 1, two of them being close to the limit between Risk Groups 1 and 2.