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

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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 bucco-lingually to obtain two separate halves of each tooth. The buccal

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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×sr) 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]

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

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:

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

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 $\leq$1000 s or $\geq$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

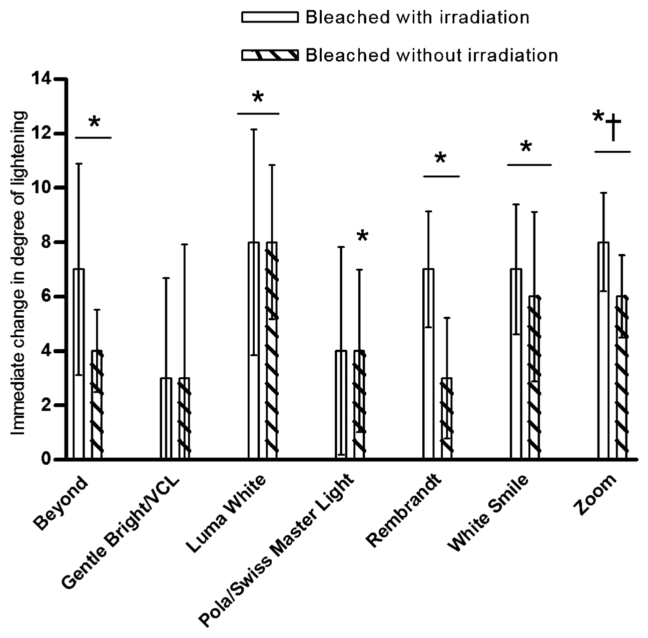

Fig. 1 Mean and 95% confidence interval of immediate changes in degree of lightening of extracted teeth after bleaching procedure with and without irradiation. †: Statistically significant difference between teeth bleached with and without irradiation, $p < 0.05$. *: Statistically significant difference 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]

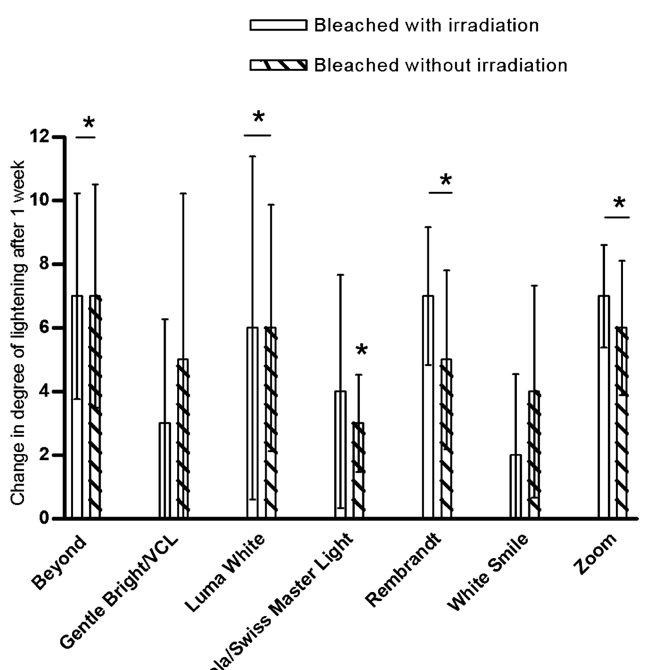

Fig. 2 Mean and 95% confidence interval of 1 week post-treatment changes in degree of lightening of extracted teeth after bleaching procedure with and without irradiation. * and n: see Fig. 1.[20]

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).

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	—[e]
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.

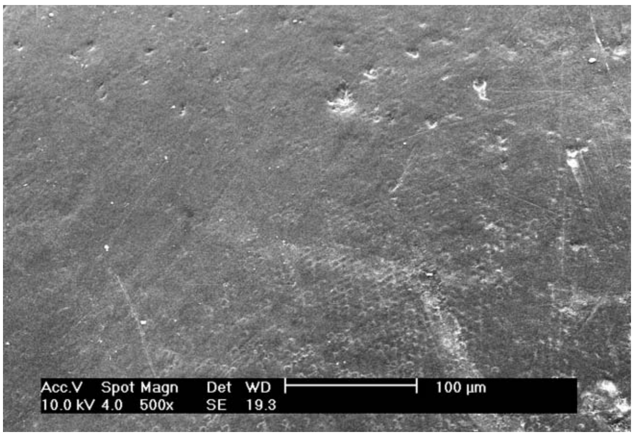

Fig. 3 SEM image of enamel surface of control (unbleached) tooth.

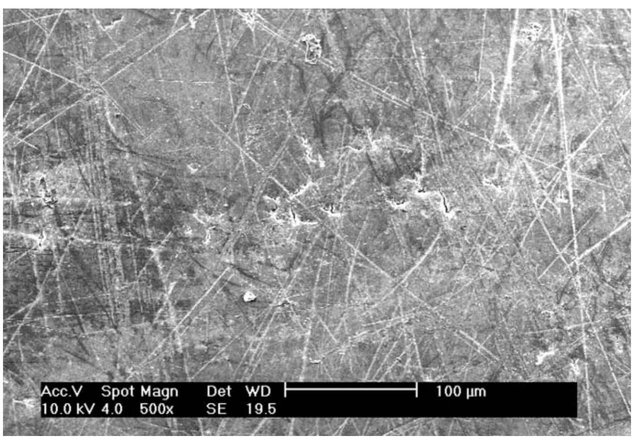

Fig. 4 SEM image demonstrating "scratched" surface of bleached tooth 2 weeks post-treatment.

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(λ)-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.

Table 3 Clients' eye exposure to direct blue light from bleaching lamps expressed as maximum permissible exposure duration (t_{max})/min (—: no measurement performed)

Radiometer	Lamp (manufacturers' recommended treatment time/min)							
	Beyond Whitening Accelerator (24)	BriteSmile (60)	Luma Cool Whitening System (24)	Remecure CL-15 Curing & Whitening Device (60)	Sapphire with Sapphire Crystal (60)	Swiss Master Light (0.2 per tooth)	VCL Complete (0.5 per tooth)	Zoom! (60)
Spectral	35	—	278	24	42	37	2	5[a]
Broadband	—	31	—	20	—	—	—	6

[a] Mean of four measurements.

Table 4 Exposure limit assessment for direct UV radiation from bleaching lamps (see Method sections 3.4.3 and 3.4.3.1) expressed as exceeding of t_{max} (within relevant treatment time) and exceeding TLVs. Values pertain to clients' eye (cornea) and skin exposure (—: no measurement performed)

Radiometer	Biological target, exposure limit assessment	Distance to target/cm	Lamp (manufacturer's recommended treatment time/min)			
			Remecure CL-15 Curing & Whitening Device (60)	Sapphire with Sapphire Crystal (60)	VCL Complete (0.5 per tooth)	Zoom! (60)
Spectral	Eye and skin, t_{max} exceeded [a](yes/no)	0	no	no	no	yes[b]
	Eye[c], TLV exceeded (yes/no)	5	yes	yes	yes	yes[d]
Broadband	Eye and skin, t_{max} exceeded [a](yes/no)	0	no	—	—	yes[b]
		5	no	—	—	yes[b]
	Eye[c], TLV exceeded (yes/no)	5	yes	—	—	yes[d]

[a] t_{max} exceeded within relevant treatment. [b] t_{max} exceeded after 5 min at 0 cm for spectral measurement and after 7 and 24 min at 0 and 5 cm distance, respectively, for broadband measurements. [c] TLV is estimated from unweighted dose and pertains to eyes (cornea). [d] TLV exceeded up to 30 cm.

Table 5 Number of successive treatments before t_{max}[a]/min was reached for reflected blue light from bleaching lamps. Values pertain to exposure of operators' eyes. Estimations assume a distance of 30 cm from reflecting surface to eyes of operator (—: no measurement performed)

Radiometer	Lamp			
	BriteSmile	Remecure CL-15 Curing & Whitening Device	Sapphire with Sapphire Crystal	Zoom!
Spectral	—	≈4	≈8	<1
Broadband	≈6	≈4	—	≈1

[a] Exposure limits for $t < 10^4$ s was used to calculate t_{max} for reflected light.

Discussion

1.0 Efficacy of light-assisted bleaching

Since changes in shade as perceived by the eye is the aim of tooth bleaching, the controlled and experienced use of shade guide tabs was considered a sufficient method. However, several disadvantages using this guide relative to the use of spectral measurements have been described.[21] Some observed teeth shades in this study did not correlate with any of the existing shades on the Vita Shade Guide, as described in Materials and methods (section 1.3), and in a few instances, the observed tooth shades were lighter than the lightest shade (B1) on the guide.

Generally, there were large variations in bleaching susceptibility, as expressed by the 95% confidence intervals, among the different

Table 6 Risk group classification of bleaching lamps based on CIE standard.[19] L_B: retinal blue-light hazard; E_S: actinic ultraviolet hazard; E_{UVA} near-UV hazard

Exposure limit function	Lamp							
	Beyond Whitening Accelerator	BriteSmile	Luma Cool Whitening System	Remecure CL-15 Curing & Whitening Device	Sapphire with Sapphire Crystal	Swiss Master Light	VCL Complete	Zoom!
L_B	1	1	1	1	1	1	1/2	1/2
E_S	E	E	E	E	E	E	1	1
E_{UVA}	E	E	E	E	E	E	1	1/2

E: Exempt group; 1: Risk group 1; 1/2: Borderline risk groups 1 and 2.

bleaching products assessed (Fig. 1, 2). A number of six teeth (7%) failed to respond to the bleaching treatment. The same resistance rate has been observed for bleaching of artificially stained teeth.[22] Other peer-reviewed published reports of resistance to bleaching with hydrogen peroxide are unknown to the authors.

The results in the present study showed that optical radiation did not influence the outcome of bleaching one week post-treatment. Lack of or limited efficacy with the additional use of optical radiation was reported in several *in vitro* studies.[23–25] These findings are also in line with clinical observations.[26–29]

In our study, radiation doses varied by a factor 3000 (Table 2), indicating lack of treatment optimisation. A study of the decomposition rate of H_2O_2 by heat and light from bleaching lamps showed that decomposition took place regardless of the presence of heat and/or light.[30] Since an improved effect of irradiation was not observed, it is likely that H_2O_2 was responsible for the bleaching effect.

In some cases, it is possible that heat emission from the bleaching lamp causes dehydration of the teeth resulting in increased lightening immediately after the treatment (Fig. 1, 2).[31] Heat can be produced from several processes: Emission of infra-red irradiation, heat exchange from the lamp components and by non-specific absorption of visible light/UV energy. The lamps in the present study emitted only negligible infra-red radiation (Table 2), but the two other processes are likely to occur. The distance between the light guide and the tooth surface is crucial for the heat exchange. For the lamps in the present study, this distance is shortest for the Remecure lamp (White Smile bleaching system) and largest for Zoom (Table 2). The combination of a short irradiation distance and a relatively high irradiance causing dehydration may partly explain the loss in bleaching efficacy observed after one week for the White Smile/Remecure system (Fig. 2).

2.0 Evaluation of tooth surface

Normally, the enamel surface is covered by a protein-rich pellicle that masks the appearance of the perichymata, and the polishing of the teeth prior to the experiments did not remove the pellicle completely (Fig. 4). The bleaching procedure seemed to further remove this pellicle as more perichymata were exposed after bleaching. Similar observations have been made previously.[7,8,32] In addition, the bleaching enamel appeared more vulnerable to mechanical stress as scratches were frequently seen, probably from the cleaning procedure after the bleaching. An explanation can be the reduced microhardness of enamel reported after tooth bleaching both by extensive exposure[33,34] and by clinically relevant exposure.[7,35,36] Since optical radiation exposure did not cause additional bleaching effect or increased the H_2O_2 decomposition,[30] it is also unlikely to see increased detrimental effect to the tooth surface.

3.0 Radiation risk assessment

3.1 Method. Radiant exitance was derived from irradiance measurements at a distance where the light field appeared homogeneous instead of flux measurement close to the source. Reflectance was assumed to be wavelength-independent. Previous estimates of reflection from teeth reaching the eyes of curing lamp operators and patients were 10–30%.[9] A further discussion of the choice of 30% reflection can be found elsewhere.[16]

3.2 Guidelines interpretations. Most countries follow international guidelines on optical radiation, such as those from *e.g.* International Commission on Non-Ionizing Radiation Protection (ICNIRP) and American Conference of Governmental Industrial Hygienists (ACGIH). These guidelines[13,14,17,18] used for risk assessment in this study apply to occupational and general exposure. Exposure that can be considered part of a medical procedure is excluded from the guidelines. Thus, concerning the person receiving treatment, there is a question whether light-assisted tooth bleaching can be considered as medical or aesthetic treatment. In the latter case, guidelines for a member of the general public apply. In the context of this study, the term "general exposure" was applied to the exposure experienced by a person who is treated solely for aesthetic reasons. Thus, the expression "client" was chosen as the most appropriate. Furthermore, the term "occupational exposure" used in the guidelines was applied to the exposure experienced by a lamp operator.

The two exposure groups in this study were subject to different exposure situations. The clients, on one hand, may be exposed to up to 60 min of irradiation to the teeth and mouth area. The irradiation may, depending on the position of the lamp, be reflected to other parts of the face and to the eyes when eye protection is missing or inadequate. Irradiation can potentially reach the eye from underneath the eye protection. Operators of bleaching lamps may be dentists and other dental personnel, hair-dressers and beauty clinic workers. These professions' exposure on the other hand, will vary considerably depending on their work and protection habits. An example of an extreme situation is when operators without eye protection sit close to one or more of the clients for frequent monitoring during treatment. These operators may be exposed to reflected irradiation for several hours per day. By the same reasoning, a low- or non-exposure situation will be experienced for operators wearing eye protection, keeping a long distance to the light source and monitoring the client only when the light is switched off between irradiation intervals. In order to arrive at representative exposure conditions, a work-task analysis may be performed.[37]

Nordic Institute of Dental Materials† recommends that tooth bleaching requires an odontological diagnosis and, as such, is carried out in a dental office or is supervised by a dentist. Lack of or limited efficacy in light-assisted bleaching in this and other studies[6,23,24,26–29,31] indicate that irradiation should not be included in the bleaching treatment. This conclusion is in line with the radiation protection principle stating that radiation shall not be used unless the effect is properly documented.[38] Thereby, light-assisted bleaching procedures carried out by non-health professionals for purely cosmetic reasons should be discouraged due to potential risk of exposure to optical radiation. The Norwegian regulations state that only health personnel are entitled to operate light therapy apparatus.[38]

Theoretically and ideally, the target of light-assisted bleaching is teeth only. In reality, irradiation is reflected and scattered to other

† Nordic Institute of Dental Materials (NIOM) provides scientifically based information and services to government health authorities, dental professionals and the public in the Nordic countries in the field of dental biomaterials.

tissues and organs as well. This involuntary exposure of tissues other than the target, together with the fact that the client cannot readily move away from the irradiation source or easily express feelings of discomfort, justify a strict assessment of the optical radiation guidelines.

3.3 Practical implications of estimated t_{max} and TLVs. Estimations of t_{max} for direct blue light is based on qualities of the light source, *i.e.* the radiance, and as such is independent on the distance to the target.[17] In the clinical situation, it is difficult to assess to what extent direct or scattered light reaches the eyes of the client. Factors influencing the exposure to the eyes are positioning and dimensions of the lamp and the avoidance behaviour of the client. The ICNIRP Guidelines state that "for evaluation of both the retinal thermal hazard and the blue-light photochemical hazard, a closest viewing distance of 100–200 mm from the apparent source can usually be assumed to represent the worst-case exposure situation".[17] This distance is twice the typical distance from the lamp to the eyes of the client in the case of light-assisted bleaching (approximately 50–100 mm).

The estimated t_{max} and TLVs for UV exposure (Table 4) were based on distances that may model the exposure situation for clients. A distance close to 0 is relevant for exposure of the mouth area and oral tissues, such as unprotected gingiva, tongue, buccal mucosa and lips. A distance of 5 cm is relevant for the eyes, cheeks, chin and nose. These distances are too short to suspect exposure of an operator in any situation. However, it is worth noting that direct UV exposure from one of the lamps caused excess of TLV up to a distance of 300 mm (Table 4).

In the estimations of t_{max} of reflected blue light (Table 5), the requirement of exposure durations less than 10^4 s (2.8 h) was used.[17] This fact may seem to be in conflict with the presentation of the data as the maximum number of treatments before t_{max} was reached within an 8 hour work-day. When the exposure limit guidelines were strictly applied, only one lamp (Zoom) exceeded the blue-light hazard weighted radiance limit of 10 mW $cm^{-2} \times sr^{-1}$ for exposure times above 10^4 s. However, since it is possible to be exposed to reflected blue light throughout the entire work-day and the risk to the eye will not be less after longer durations than 10^4 s, it was considered useful and informative to choose exposure limits for shorter durations.

3.4 Biological implications. Effects on the eye by UV radiation and visible light are well documented.[39,40] A discussion of biological effects due to exposure of visible light from dental optical radiation sources can be found elsewhere.[16,41]

No guidelines exist on optical radiation exposure to mucosa. It is unknown whether oral tissues have undergone the same evolutionary adaptation towards UV exposure and thereby possess the same protective mechanisms as skin. Factors that may indicate that oral mucosa is more sensitive to UV than is skin and thus favour cautious intra-oral use of UV, are the following: difference in tissue thickness, unknown adaptive responses such as pigment darkening and tissue thickening effect, and unknown DNA repair capacity and apoptotic response (*e.g.* sunburn cell formation in skin). Particular malignancies known to be induced by UV, *e.g.* squamous cell carcinoma, behave more aggressively in the mouth than in skin. UV and blue light exposure can also give rise to photosensitisation reactions through endogenous (*e.g.* porphyrins, flavins) and exogenous (*e.g.* drugs, dental materials, cosmetic products) molecules inside the oral cavity. The UV exposure of uncovered skin by one lamp in this study resulted in average t_{max} of 4 min (Table 4). For comparison, this value is 1/4 of the t_{max} obtained for UV exposure by midday, midsummer sun at 60° N (UV index = 6). It is unlikely that oral tissue will be exposed to UV as frequently as sun-exposed skin. However, reports in the popular press suggest that some clients repeat light-assisted bleaching treatment as often as every six weeks. Repetitive bleaching treatment incidence is not documented, but marketing indicates that treatment should be repeated once a year or every other year.

In conclusion, optical radiation of wavelengths between approximately 370 and 700 nm and radiation doses of 1–2500 J cm^{-2} did not improve bleaching efficacy relative to bleaching without irradiation. The use of optical radiation in tooth bleaching poses a health risk to the client and violates radiation protection regulations. Therefore, we will advise against light-assisted tooth bleaching. When bleaching lamps are still used, adequate eye and skin protection should be used by client and operator.

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