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Optical hazard of solar radiation on the dilated eye

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HIGHLIGHTS

The energy absorbed by the dilated eye exceeds the safety thresholds defined by the Standards for artificial light sources, the risk of retinal lesions posed by indoor artificial light sources is negligible contrary to the solar radiation, the threat is not clearly presented to people undergoing medical treatment.

ABSTRACT

Administration of drops to dilate pupils is a common medical procedure around the world prior to an eye examination. Drops cause clinically significant dilation of the pupil (mydriasis) and inhibit its response to the visible wavelengths [1, 2]. The energy absorbed by the retina is proportional to the aperture size [3], therefore the risk of a lesion increases with the diameter of the pupil [4]. There are a vast number of approved drugs, which brochures warn patients about potential risks. Not all mentions protecting eyesight from the light [5–7]. None of them indicate the solar radiation, the sun, the sunlight or similar as potential hazard. Within this research, I adopt international standards for artificial light sources [4, 8] to define the safety class and risk group for the solar radiation affecting the dilated eye. The solar radiation is hazardous, following standards' thresholds [4, 8]. I indicate a lack of clarity and a single-minded approach in the drugs' characteristics regarding this specific hazard. I encourage drug producers and medical society to validate this risk.

Key words: pupil dilation, dilated eye, solar radiation, sunlight

DEFINITIONS

Q_{sun} – the direct and circumsolar solar spectrum AM 1.5 given from [9].
L_{λ} – the spectral radiance of the source (sun) ($W \times m^{-2} \times sr^{-1} \times nm^{-1}$).
α – the angular subtense of the sun (9.3 mrad).
$R(\lambda)$ – the burn hazard weighting function.
Δλ – the bandwidth (1 nm here assumed).

INTRODUCTION

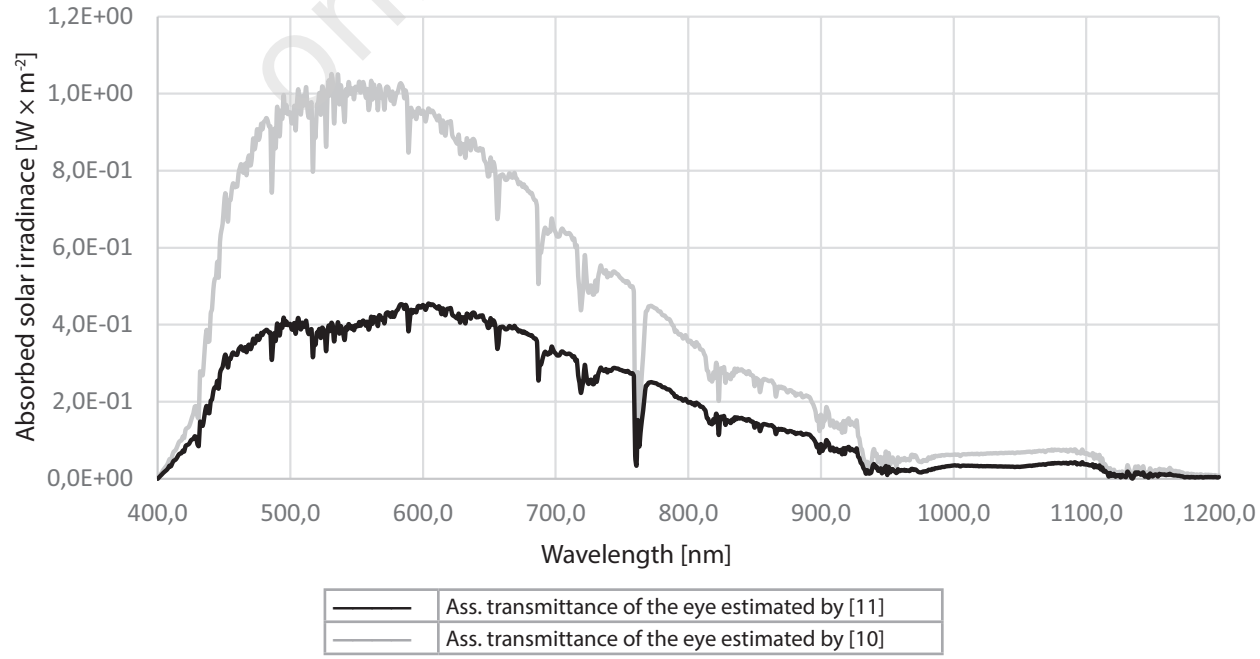
Dilation of the pupil (mydriasis) for an eye examination is a very common medical procedure worldwide. Assuming that statistically every person with access to basic health care system undergoes it few times during the lifetime it total number could be estimated at hundreds of millions per year. There are numerous eye-drops (anticholinergics and mydriatics) that administered to patients of various age cause the mydriasis, which lasts much longer than an eye examination. Consequently, the patients leaving the building are exposed to external conditions while no longer under the care of a physician. Only selected producers are indicating the need to protect the dilated eye from "light" or "bright light" within the precautions and warnings section of the drug characteristics. None of the identified medicines is mentioning the solar radiation as the hazardous source. Within this work, I investigate the risk of retinal lesions of the dilated eye due to direct intrabeam viewing of the sun. I apply international standards for artificial light sources as the reference ones regarding the warnings and precautions.

OPTICAL CHARACTERISTICS OF THE HUMAN EYE

Visible wavelengths within the 400 nm to 780 nm are a special hazard to the eye because the very properties necessary for the eye to be an effective transducer of light correspond to high radiant exposure of the retina (fig. 1). Geeraets and Berry [10] as well as Boettner and Wolter [11] have estimated spectral transmission of the ocular media of the human eye. The first measured spectral transmission using enucleated eyes, while the latter measured transmission factors separately for the cornea, aqueous, lens, and vitreous. There is a considerable difference in the results obtained within those two approaches. Furthermore, Geeraets and Berry [10] also measured fundus reflectance and the absorption in the human retinal pigment epithelium. Sliney and Freasier [3] presented absorption in the human retinal pigment epithelium proportional to [10] with Boettner and Wolter [11] as input values. Consequently, I have plotted the solar spectrum [9] of the energy absorbed by the retina over the visible wavelengths within the spectral region 400 nm to 1200 nm in figure 1. Sliney and Freasier [3] concluded that higher values may be considered for large image sizes, while lower values are probably more reasonable for smaller image sizes. Unfortunately, the experimental techniques used did not allow a clear indication of the comparable image sizes for each curve.

FIGURE 1

Retinal absorbed solar irradiance.



RETINAL LESIONS HAZARD

The sunlight is absorbed by the pigment called melanin contained in the pigment epithelium. It will cause local heating and will affect the pigment epithelium and the light-sensitive rods and cones. Consequently lesion may result in temporary or permanent loss of vision depending on the magnitude of the exposure [4]. A visual decrement will usually be subjectively by an exposed individual only when the central or foveal region of the macula is involved. The fovea is the most important part of the retina, as it is responsible for the sharpest vision. The visual angle subtended by the fovea is approximately equal to that subtended by the sun. If this region is damaged, the decrement may appear initially as a blurred white spot that obscures the central area of vision; however, within two or more weeks, it can change to a black spot. Some may not be aware of this blind spot (scotoma) during normal vision. However, it can be revealed immediately on looking at an empty visual scene such as a blank sheet of white paper. Peripheral lesions will only be subjectively registered when gross retinal damage has occurred. Small peripheral lesions will pass unnoticed and may not even be detected during a systematic eye examination [4].

The pupil is to limit the amount of radiant energy entering the eye, hence reaching the retina. The energy absorbed is proportional to the size of the pupil. For the outdoor (daylight) adopted eye the pupil diameter is equal to 2–3 mm [3] (for momentary viewing of the sun – 1.6 mm). Anticholinergics and mydriatics cause clinically significant dilation of the pupil, which inhibits its response i.a. to the bright light. Consequently any risk associated with this drug effect should be indicated within product characteristic of the drug.

CHARACTERISTICS OF MEDICATION

There is limited access to the proceedings and results of clinical tests, which have to be conducted and approved by national and international medical/drugs agencies/authorisation centres to introduce the medication on the market. On the basis of European requirements, when a new drug is of similar quality and essentially similar to the reference drug, the producer/distributor may avoid some studies. The statement that a new product is a generic solution and contains the same amount of active substance as the reference medicine is only needed. Then it is even more difficult to conduct research, as older documentation, related to the reference drug is already archived with limited or no public access. Consequently, this study cannot prove nor deny that some manufacturer or distributor has issued and conducted clinical tests on an optical hazard caused by the sun. Only the information presented in the product characteristics or the package brochure is public. Those are mentioning the optical hazard, in my opinion, in general without paying due attention to the danger of the solar radiation specifically. To broaden the research, not only eye drops characteristics have been investigated, but eye-injections medications as well, with the same clinical results.

Note that the documentations here quoted have been selected randomly, and there is no intention to point out any specific producer or distributor. My objective is to present a broad scope of documentation from various regions of the world. My assumption is that the characteristics of similar drugs are almost the same to the ones here presented in the scope of possible side effects and adverse reactions as well as warnings and precautions for patients.

All identified within this research drugs' characteristics indicate of sensitivity to glare/photosensitivity (photophobia) as a possible side effect [12] or an adverse reaction [2, 5] or other paragraphs [1, 6, 13]. Selected include warnings and precautions:

- "[…] *it is recommended to wear sunglasses to protect the eyes from the effects of ultraviolet radiation*" [12]
- "*Patients* […] *should protect their eyes in bright illumination when pupils are dilated*" [2]
- "[…] *you should protect your eyes from bright light.*" [7].

None are literally mention the sun, sunlight, direct solar radiation or similar as potential source of hazard.

There are no regulations that discuss this optical hazard specifically. Consequently the only available standards for artificial light sources (lasers and lamps) could be applied.

METHODS

IEC 60825 [4] and IEC 62471 [8] are international standards for the *safety of laser products* and the *photobiological safety of lamps and lamp systems*, respectively. Both main objectives are to protect people from optical radiation hazards, reduce the possibility of injury, and ensure adequate warnings. Both standards introduce classes of safety starting form no hazard AEL class 1 for [4] and Risk Group 0 for [8] to hazardous AEL class 4 and Risk Group 3, respectively.

It is important to note that in both standards assumed the aperture diameter of the aperture (the pupil) equals 7 mm, while [14] states that the pupil diameter after dilatation may reach up to 9 mm, and the results obtained in [15] up to 8 mm. However Goel [15] states: "*one drop of tropicamide 1% was used to standardise the process, whereas in the clinical scenario stronger and increased number of drops may be used for achieving maximal dilation.*". The results of the clinical trials presented in [16] have shown that the maximal diameter of the pupil is 9 mm. Note that standards assume 7 mm of pupil's diameter as 'the worst case scenario', while within this work 9 mm has also been considered.

Within this work I select accessible emission limits (AEL) for visible wavelengths (400–1400 nm) extended source

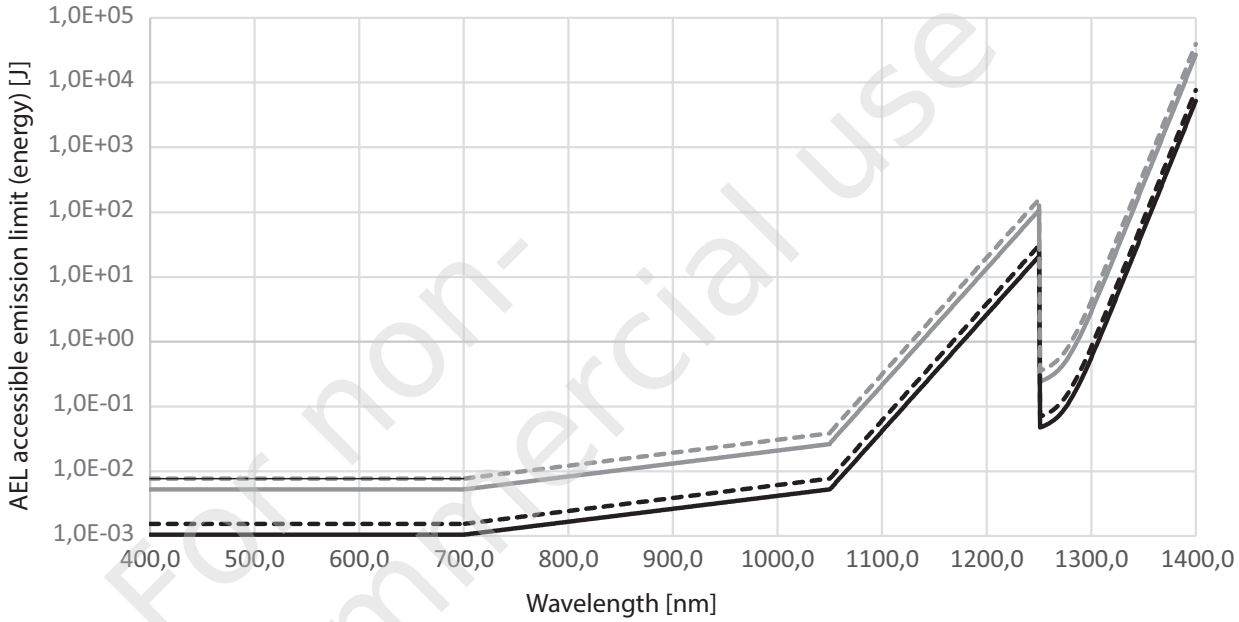
(a source with an angular subtense at the cornea more than (4)) and exposure times: t = 0.15 s and t = 0.25 s, which correspond to the blink reflex. Consequently AEL classes are presented graphically in figure 2.

RESULTS

For the Standard IEC 60825 [4] the function f(λ)=Q_(sun,λ)/ AEL(1,3(λ)) for 1 and 3R AEL classes as defined in [4] is presented in figure 4.

FIGURE 2

AEL accessible emission limits for various classes, following [4].



Note: the AEL values of class 1 as defined in [4] equal the maximum permissible exposure (MPE) limits published by the International Commission for Non-Ionizing Radiation Protection.

The solar spectrum in the range of 400–1400 nm is classified as multiple wavelengths set out as defined in [4], consequently the energies are additive to the eye. Hence, it allows to check condition for a given case by equation:

$$\sum_{\lambda=400}^{1400} \frac{Q_{sun,\lambda}}{AEL(\lambda)} \leq 1 \quad (1)$$

The Standard IEC 62471 [8] defines exposure limits (EL). It objective is to represent conditions under which it is believed that nearly all individuals in the general population may be repeatedly exposed without adverse health effects [8]. For visible light spectrum the retinal burn hazard weighting function is predetermined. This function is presented in figure 3.

To protect against retinal thermal injury, the integrated spectral radiance of the source (here, $Q_{sun,\lambda}$ considered), weighted by the burn hazard weighting function $R(\lambda)$ (from fig. 3) must not exceed the levels defined in [8] by equation:

$$L_R = \sum_{380}^{1400} Q_{sun,\lambda} \times R(\lambda) \times \Delta\lambda \leq \frac{5000}{\alpha * t^{0.25}} \quad (2)$$

	AEL class	Exposure's time (s)	Aperture Ø (mm)
———	1	0.15	7
----------	1	0.25	7
———	3R	0.15	7
----------	3R	0.25	7

$$\sum_{\lambda=400}^{1400} \frac{Q_{sun,\lambda}}{AEL(\lambda)},$$

called the class condition, has been calculated for all above considered conditions and results are presented in table 1.

TABLE 1

Class conditions validation for various exposure times and aperture.

No.	AEL class	Exposure's time (s)	Aperture Ø (mm)	Class condition	
1	1	0.15	7	2.92	Not fulfilled
2	1	0.25	7	3.32	Not fulfilled
3	3R	0.15	7	0.58	Fulfilled
4	3R	0.25	7	0.66	Fulfilled
5	3R	0.25	9	1.1	Not fulfilled

Table 1 brings us to a conclusion that the conditions for cases 1, 2 and 5 are not fulfilled, while the conditions for cases

FIGURE 3

Retinal burn hazard weighting function for time exposures, source [8].

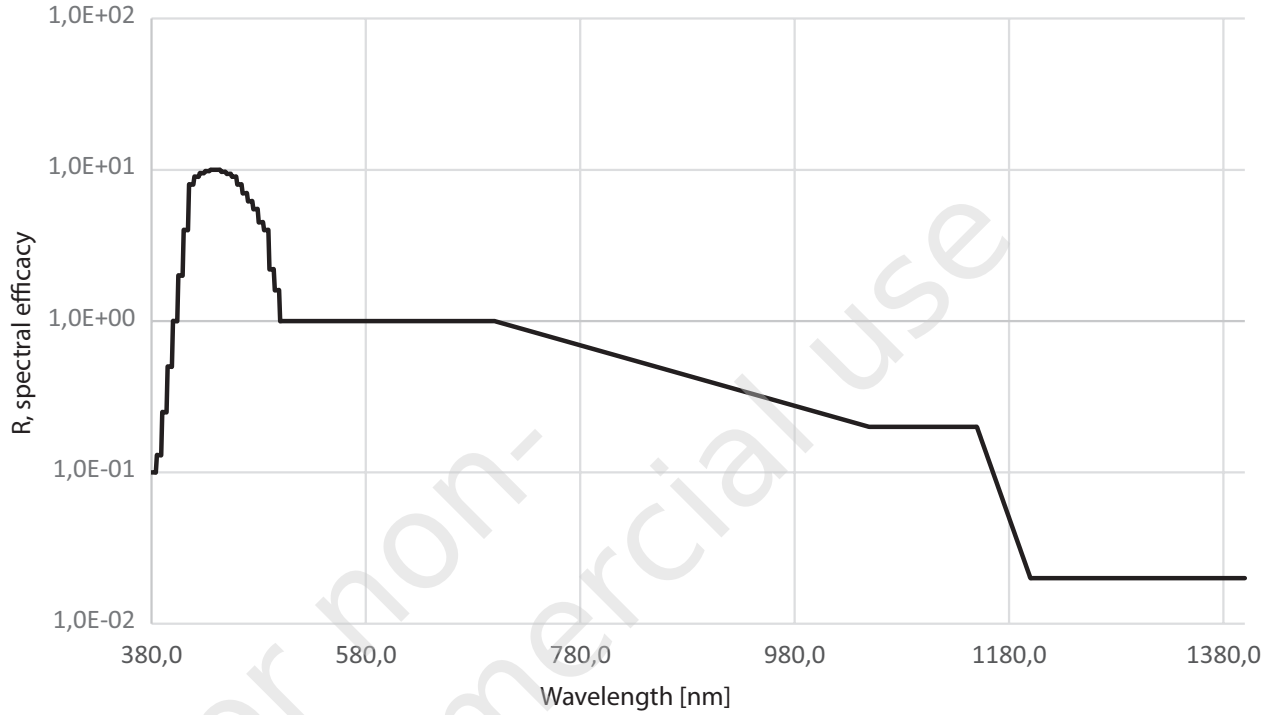
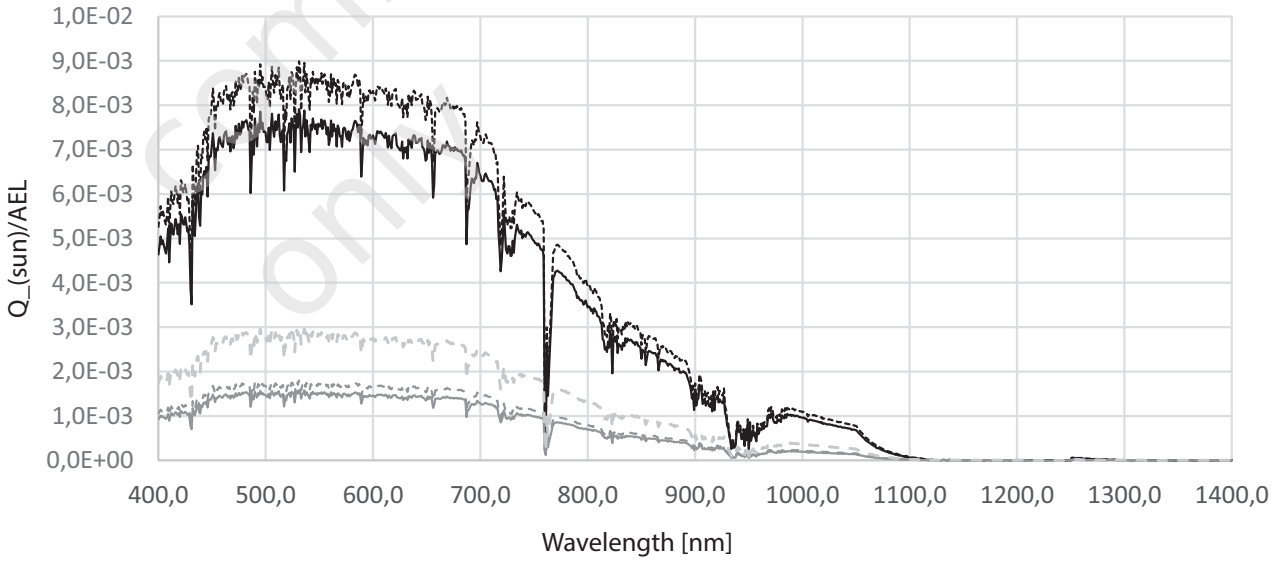


FIGURE 4

AEL class conditions as defined in [4] for solar spectrum.

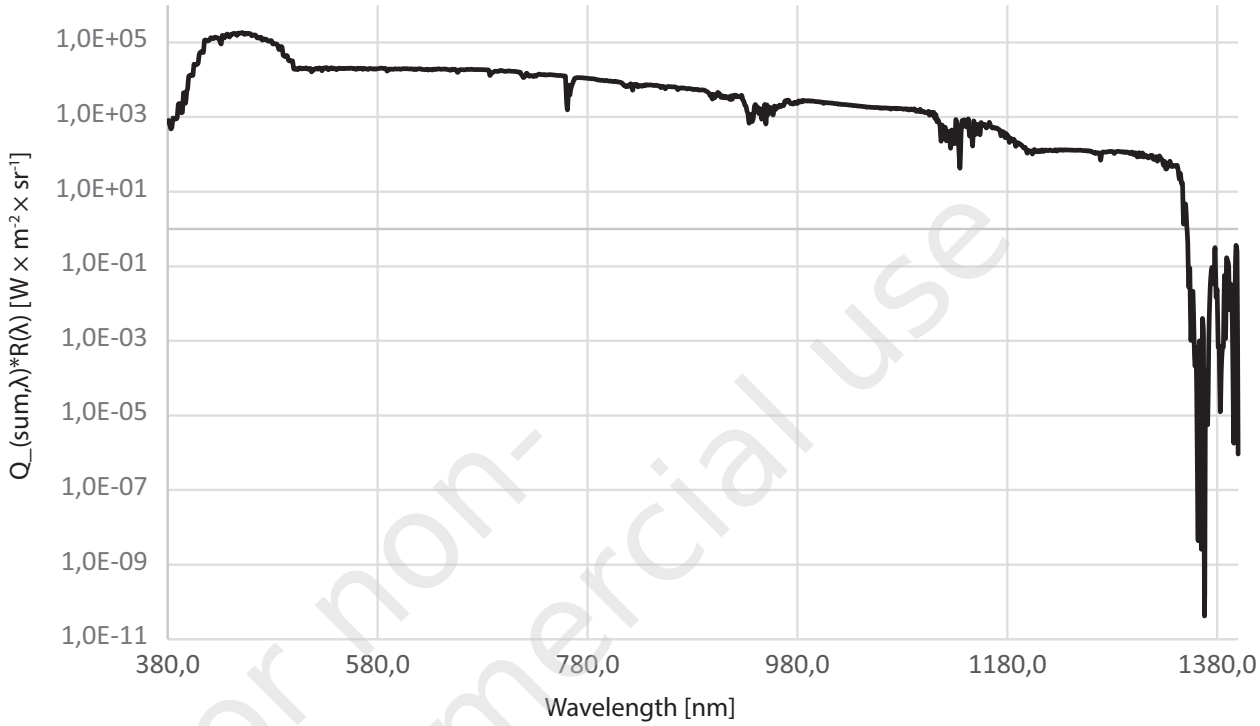


3 and 4 are fulfilled. As defined in [4] when the condition for a given class is not fulfilled, then the upper class must be applied. Consequently, for conditions 1–4 AEL of class 3R is valid and for condition 5 class 4 should be applied.
For the Standard IEC 62471 [8] the function $f(\lambda)=Q_{(sun,\lambda)}\times R(\lambda)$ is presented in figure 5.

	AEL class	Exposure's time (s)	Aperture Ø (mm)
———	1	0.15	7
----------	1	0.25	7
———	3R	0.15	7
----------	3R	0.25	7
----------	3R	0.25	9

FIGURE 5

Solar spectrum weighted by the retinal burn hazard function R(λ) as defined in [8].



When data from the figure 5 are integrated over the spectrum considered the condition presented in Eq. (2) is not fulfilled for both cases:
$L\_R=1.72\times10^7$ is bigger than 8.64×10^6 for t = 0.15 (s), and
$L\_R=1.72\times10^7$ is bigger than 7.6×10^6 for t = 0.25 (s).

Hence, one may state that this source poses a retinal thermal hazard within the aversion response (blink reflex) for the Risk Group 2 (Moderate-Risk) classification as stated in [8]. Consequently, the source should be classified into Risk Group 3 (High-Risk).

DISCUSSION

As I have presented the energy absorbed by the dilated eye exceeds the safety thresholds defined by the Standards: IEC 60825 as well as IEC 62471. The sun as the source is categorized within Class 3R, or even Class 4 for a given time/aperture conditions, and High-Risk Group following [4] and [8] regulations respectively. As defined by [4]: Class 3R sources "*should only be used where direct interbeam viewing is unlikely.*". Class 4 is the source "*which interbeam viewing* […] *is hazardous and for which the viewing of diffuse reflections may be hazardous.*". As defined in [8]: Risk Group 3 (High-Risk) is the source which "*may pose a hazard even for momentary or brief exposure.*".
Simultaneously, research carried out by [17, 18] showed that most indoor LED lamps and luminaires are classified in Risk Group 1 (Low-Risk) or Risk Group 0 (No-Risk) and therefore they do not pose an ocular hazard. Taking all available scientific data into account, SHEER Committee [19] concluded that there is no evidence of direct adverse health effects from LEDs emission in normal use (lamps and displays) by the general healthy population.
Maximum effect of the mydriasis occurs within 60 min after instillation of an eye drop. Clinically significant dilation, inhibition of pupillary light response last 3 h, with recovery beginning at approximately 90 min [1, 2]. A basic eye examination last between 45–90 min. Consequently it is highly probable to be affected by the solar radiation when leaving the building after treatment with the most dilated pupils.
I present in this study that only one drug's brochure [12] recommends wearing sunglasses to protect eyes against a bright light but UV radiation has been indicated as potential hazard. As presented in figure 1 any wavelengths below 400 nm are not reaching the retina, consequently there is no relation with diameter of pupil to UV radiation affecting the retina.
There is limited public access to clinical trials, or no access at all when the documents are already archived; consequently, there is limited possibility to research and learn a vast number of studies regarding safety issues of drugs currently offered on the market.
Although all identified by me drugs' brochures and product characteristics prohibit driving the vehicles after adoption of drops until proper vision is restored, there are voices

against this prohibition. Consequently, research articles have been published that show a decrease in visual function below the acceptable standard [15] or ended with conclusions to evaluate each patient to their ability to drive [14]. In both and others like them studies, I have not found any remarks about any hazard of retinal burn caused by the long-term (longer than blink reflex) viewing the sun or its reflection i.a. from other cars. Within this research, I prove that this hazard is probably especially when driving situation forces the driver to observe the given objects, including those with a reflective surface.

CONCLUSIONS

I proved that the sun radiation, which affects the retina of the dilated eye exceeds the safety thresholds defined by the standards for artificial light sources. I showed that this hazard is not explicitly mentioned on drugs' packing envelopes, brochures nor products characteristics. Although selected drugs' descriptions are warning against "light/illumination" or "bright light/illumination", none of them is defining its specific origin although, as I present the risk posed by indoor artificial light sources is negligible contrary to the solar radiation. Some do not mentioning about the optical hazard caused by light at all. There is lack of single-minded approach within this scope.

Large-scale controlled studies are required to investigate potential lesions to the retina od the dilated eye when affected by the solar radiation. Due to limited access to the clinical trials' proceedings and results there is no possibility to verify, if such hazards have been already studied.

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Ethics:
The content presented in the article complies with the principles of the Helsinki Declaration, EU directives and harmonized requirements for biomedical journals.