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Ophthalmic instruments — Background for light hazard specification in ophthalmic instrument standards

Instruments ophtalmiques — Contexte des spécifications du risque lumineux dans les normes relatives aux instruments ophtalmiques

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Foreword

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Introduction

Light tissue damage is mechanical, thermal or chemical. Mechanical injury such as that from a laser is a disruption, fragmentation or vaporization of tissue. Photothermal injury is the conversion of light energy into heat. In photochemical injury (actinic) a photosensitized molecule reacts directly with target tissue in a Type 1 (free radical) reaction, or with molecular oxygen to produce singlet oxygen or super oxide which in turn reacts with target tissue in Type 2 (photodynamic) reactions. Photochemical retinal injury without exogenous photosensitizers (phototoxicity) usually occurs with prolonged exposure to light levels that are tolerated with shorter exposure times. These mechanisms are not mutually exclusive but can occur simultaneously or sequentially.

There are at least two basic types of acute experimental retinal phototoxicity. The first is the acute blue-green phototoxicity that Noell discovered in 1966. Rhodopsin mediates this type of damage and also scotopic vision. Rhodopsin absorption peaks around 507 nm (blue-green), so scotopic sensitivity and Noell's phototoxicity are highest in the blue-green part of the spectrum. The second is the acute UV-blue phototoxicity that Ham et al discovered in 1976. Its severity increases with decreasing wavelength, so UV radiation is potentially more hazardous than violet light which in turn is potentially more hazardous than blue light. In 1978, Mainster showed that clear PMMA intraocular lenses transmitted potentially hazardous UV radiation to the retina between 330 nm and 400 nm. By 1986 most intraocular lenses had UV blocking chromophores to protect patients.

Staring at the sun can cause acute UV-blue phototoxicity. Operation microscopes and endoilluminators can cause acute macular injuries with brilliant illuminance of 20 000 lx or more. Epidemiological evidence linking age-related macular degeneration (AMD) to lifelong light exposure is currently inconclusive. Evidence showing a link between cataract surgery and progression of AMD is confounded by pseudophakes' intense operating microscope exposure during surgery and the fact that the risk of AMD is increased in cataract patients. Intraocular lenses that block violet and blue light in addition to UV radiation have recently been introduced. Their use is controversial because there is no clinical evidence that it decreases the risk of AMD and they partially block blue light that is useful for older adults' declining scotopic vision.

There are a wide variety of ophthalmic instruments that direct optical radiation into the eye for various applications. The term "optical radiation" includes ultraviolet, visible and infrared radiation. In its widest use, the term optical radiation covers the wavelength range of approximately 100 nm to 1 mm. While there are a number of product performance and user standards that are applicable to products that emit optical radiation, they cover only the region of interest from 250 nm to 2,5 µm.

Ophthalmic instruments can be used for diagnosis and treatment as well as for measurements, monitoring and observing the eye. New ophthalmic instruments using optical radiation are always being developed. Many ophthalmic instruments use intense optical radiation that is potentially hazardous. It is well known that optical radiation of sufficient intensity is capable of producing ocular damage. There have been numerous reports of ocular damage from the optical radiation emissions not only from the sun, but also from operation microscopes and endoilluminators used during ocular surgery as well as from lasers. See Bibliography [1] to [31]. While the majority of injuries from operation microscopes and endoilluminators produce minimal symptoms, scotoma and permanent central vision loss have occurred in some patients. See Bibliography [11].

In the case of photochemical damage, clinical changes are not immediately evident. Retinal edema or mild pigmentary changes are typically seen within one or two days of exposure and varying degrees of pigmentary modelling become more visible after one to three weeks. See Bibliography [18]. This is true with all photochemical damage. It should also be noted that it has been shown that photochemical damage follows a dose-response relationship with the risk of retinal damage increasing with increasing retinal exposure. In the case of operation microscopes, some studies have indicated that retinal injuries may occur with exposure times ranging from 20 min to 120 min, although a recent study suggests that retinal injuries can occur in exposure times of shorter duration. See Bibliography [49]. While the incidence of serious injury is unknown, it appears to be infrequent. There is yet more subtle damage that may occur that may not be noticeable or visible as a retinal lesion.

It should be noted that modern ophthalmic instruments use increasingly efficient light sources, such as tungsten, xenon and metal halide lamps. The emissions from such lamps have a higher colour temperature and emit significantly more blue light as well as ultraviolet radiation than those from traditional tungsten filament lamps. Unlike the older lamps, the light output from the new lamps does not diminish significantly in intensity throughout their longer life. See Bibliography [1]. Further, the optical radiation emissions from these new lamps can present a real hazard to the eye. As a result, ophthalmic instruments being used to examine or treat an eye can create the risk of physical damage to that eye. In this regard, studies show that the optical radiation emissions from some common ophthalmic instruments can exceed safety guidelines in relatively short exposure times. See Bibliography [19] and [36]. Those most at risk may be the elderly and infants, especially those with diseased eyes. The risk increases the longer the eye is exposed to the light. Ironically, it is generally the patient whose eye is not healthy that requires the longest examination. Since some ophthalmic instruments clearly present a risk of retinal damage and others present a potential risk for retinal damage, a number of safety performance standards have been developed.

Standards exist for the optical radiation safety of lamps and lamp systems (CIE S-009E:2002[53], IEC 62471:2006[56]) as well as a number of standards for the performance and safe use of lasers (e.g. IEC 60825-1[54] and IEC 60601-2-22[55]). Optical radiation safety limits for ophthalmic instruments are included in the performance standards for some of these instruments. Finally, there are standards for optical radiation safety in the work environment. However, there is no single comprehensive standard applicable to all ophthalmic instruments that direct optical radiation into or at the eye.

ISO 15004-2[52] has been developed to fill that void. It will be applicable to all ophthalmic instruments that are designed to direct optical radiation into or on to the eye for diagnostic or monitoring purposes. Its objective is to provide uniform requirements for such specific-use instruments. It is intended to establish minimal optical radiation safety specifications and requirements that will be useful to both manufacturers and users of the instruments.

The scope of ISO 15004-2[52] is intentionally broad. It covers ophthalmic instruments used for diagnosis of ocular disease, ocular monitoring instruments, lasers, continuous wave and pulsed light source instruments, and operation microscopes and endoilluminators. It is also intended to cover other medical diagnostic instruments such as ocular glucometers currently under development. It is not applicable to portions of instruments emitting radiation for treatment of the eye as these instruments are designed to produce damage and/or structural changes to the eye.