

Study of the effect of involuntary user movement on the potential light hazards from some ophthalmic instruments

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A study was undertaken to determine whether involuntary user movement provides a basis for relaxing the measurement conditions for evaluating the potential optical radiation hazards to the eye from slit lamps and indirect ophthalmoscopes. This was accomplished by assessment of the extent to which light from these devices can be maintained in focus on a 1-mm-diameter fiber-optic cable for 45 s. The results suggest that, although involuntary user movements can be significant, they do not provide a basis for relaxing the measurement conditions for evaluating the potential optical radiation hazards to the cornea and lens from slit lamps and indirect ophthalmoscopes. © 2004 Optical Society of America

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1. Introduction

Modern ophthalmic instruments are using increasingly efficient light sources, such as tungsten, xenon, and metal-halide lamps. The emissions from such lamps have a higher color 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.¹ Furthermore, the optical radiation emissions from these new lamps can present a real hazard to the eye. As a result, instruments that are used to examine or treat the eye can create a risk of physical damage to the eye. In this regard, studies show that the optical

radiation emissions from some ophthalmic instruments exceed safety guidelines.^{2,3} In addition, there have been numerous reports of ocular damage from the use of operation microscopes during cataract surgery.^{4–20} Those patients most at risk may include 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 patients with already unhealthy eyes who require the longest examination times.

As a means of reducing and controlling these risks, an international standard for the optical radiation safety of ophthalmic instruments is being developed by the International Standards Organization Technical Committee 172. The standard is intended to provide protection for all ocular tissues, but specifically for the cornea, lens, and retina. This is accomplished in part by the establishment of optical radiation limits. Any limits that are set, however, must be balanced with the need to ensure that the light remains white and that its intensity is sufficient to permit an accurate diagnosis to be made. They should also reflect realistic conditions of use.

An emission limit to provide protection to the cornea and lens of the eye is typically specified as the maximum radiant power detectable through a fixed-aperture stop 1 mm in diameter.²¹ In evaluating a device for conformance with standard limits, the measurement of radiant power is made with the device and the aperture in a fixed position. The reason for this is that safety limits are based on the assump-

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tion that a stationary eye is exposed to light from a stationary instrument.

When the retina is viewed with instruments such as the indirect ophthalmoscope and the slit-lamp microscope, a condensing lens, generally hand held, is used to focus the light on the plane of the crystalline lens to illuminate the retina uniformly. During a typical examination, the clinician scans the retina and makes voluntary movements with the instrument. If, however, an area of particular interest is observed, attempts are then made to maintain a stationary mode. The safety limits assume that both the instrument and the eye remain stationary during the examination. It is, therefore, appropriate to consider the extent to which involuntary user movement affects the ability of the clinician to intentionally keep the light focused on a single point for any length of time. For indirect ophthalmoscopes, which are head mounted, both involuntary head and hand movements must be considered, whereas with the slit lamp, only involuntary hand movements are involved.

It should be noted that the risk of damage to tissue at a particular point is proportional to the irradiance and exposure, or dwell time, at that point. Those tissues most at risk of damage from the focused beam of instruments such as the indirect ophthalmoscope and the slit lamp are the cornea, lens, and iris. In the case of the indirect ophthalmoscope and the slit lamp, the involuntary movements made by the clinician during an examination may cause the beam to not remain fixed on a single point, but instead to move over an area greater than a 1-mm-diameter aperture. Such movement, if significant, would result in lower integrated exposure times at any given point than would be found in a fixed condition. Thus any significant involuntary user movements associated with the use of these devices may have a significant effect on the potential optical radiation hazards to the lens and cornea. Any significant involuntary user movement also raises the question about whether test methods for these devices should be based on the assumption that the eye and the instrument are both stationary. This is important because significant involuntary user movements may provide the basis for relaxing the measurement conditions and thus effectively increasing the safety limit for these instruments. For example, if the focused beam can only be maintained within a 2- or 3-mm-diameter circle, instead of within the current 1-mm-diameter aperture specifications, then an averaging aperture of 2- or 3-mm diameter may be used to evaluate the radiation emissions from the instrument. As a result, the safety limit would effectively be increased by a factor of 4 or 9. This would, in turn, significantly reduce the burden for manufacturers to achieve compliance with the safety limits for such instruments. The purpose of this study was to explore the effect, if any, of involuntary user movement on the potential optical radiation hazards that may be associated with the use of indirect ophthalmoscopes and slit lamps.

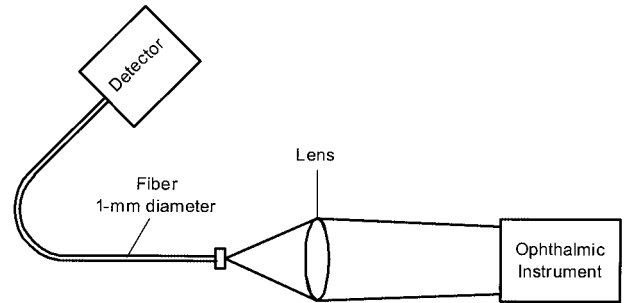


Fig. 1. Experimental setup used to focus light from an indirect ophthalmoscope and slit lamp onto the end of a 1-mm-diameter fiber-optic cable.

The experiments were designed to measure the effects of involuntary movements of the observer by determining how well these devices could be intentionally focused onto a 1-mm diameter circular spot on the cornea and lens of the eye. If involuntary user movements prevent the user from being able to intentionally focus the light onto a 1-mm spot for a reasonably short period of time, then the measurement conditions that determine compliance with safety limits should be relaxed for these devices to reflect realistic conditions of use. If this is not the case, then the measurement conditions cannot be relaxed. With this in mind, we employed two ophthalmic instruments that produce a Maxwellian view through the cornea and crystalline lens: the binocular head-mounted indirect ophthalmoscope and the slit-lamp microscope. For the indirect ophthalmoscope, we identified the effects of hand and head movements separately and then the combined effects of both.

2. Methods and Apparatus

The experimental setup used is shown in Fig. 1. The equipment consisted of a device to measure radiant energy (United Detector Technology [UDT] 40A optometer); a 1-m long clear-coated 1-mm core diameter Newport fiber optic with a flat polished surface at both ends (Model F-MMC with a step index profile and NA of 0.37); a head-mounted Heine Omega 180 binocular indirect ophthalmoscope; a Haag Streit 9000 slit lamp; and four condensing lenses (a Topcon +14D, a Zeiss +20D, an Ocular +28D, and a Volk Superfield NC +90D lens). Three condensing lenses with different focal lengths (+14D, +20D, and +28D) were used with the indirect ophthalmoscope because the focal length of the lens affects the ease with which the lens can be held steady while performing indirect ophthalmoscopy. For the slit lamp, only one lens, (+90D) was used because the focal lengths of slit-lamp lenses are very small and differ from one another by only a few millimeters.

We performed four sets of experiments with the indirect ophthalmoscope and two sets with the slit lamp. To eliminate any involuntary hand and head movements, the instrument, lens, and fiber were first mounted on an optical bench in the first set of exper-

iments. In this configuration, the light from the indirect ophthalmoscope was directed through the condensing lens and focused onto the end of a 1-mm core diameter fiber optic. The other end of the fiber was connected to a UDT 40A optometer, which was operated in the integrate mode to collect the radiant energy delivered to the detector from the fiber. The relative radiant energy collected from the fiber that was illuminated by the indirect ophthalmoscope through each lens was recorded. For all experiments data were obtained in a darkened room. An integration time of 45 s was arbitrarily selected for all the experiments.

In the second set of experiments, the lenses were hand held, and the indirect ophthalmoscope was still bench mounted. Four observers, including an experienced clinician, participated in these experiments. The task of the observers was to keep the light from the indirect ophthalmoscope steadily focused onto the end of the 1-mm-diameter fiber-optic cable. It should be noted that attempts were made to provide support to the observer's hand to reduce involuntary movements of the condensing lens and to thus simulate the action of the clinician's fingers as they are placed against the head of the patient to steady the lens. To achieve this, observers pressed their fingers against the fiber optic holder or used the bench to support the elbow of the hand holding the lens or applied both techniques.

In the third set of experiments, the indirect ophthalmoscope was head mounted, whereas the lenses remained fixed on the bench. However, the task for the observers remained the same. The goal of the second and third experiments was to assess the extent to which involuntary hand and head movements affect the amount of energy that can be collected in a 45-s time period.

The cladding on the fiber was clear; consequently, the entire fiber appeared brightly illuminated when the light was well focused onto the fiber tip. This provided additional visual feedback to the observer. Loss of brightness from within the fiber provided another dynamic cue for the observer to reposition the hand-held lens or head-mounted instrument to keep the light focused onto the end of the fiber. In this regard, the experimental design provided visual feedback somewhat analogous to that received by a clinician during an examination of the retina of the eye.

Finally, experiments were performed to assess the combined effects of involuntary user movements with the hand-held condensing lens and the head-mounted indirect ophthalmoscope, thus simulating the conditions that exist during a clinical examination. This experiment was carried out by an experienced clinician who had not participated in the experiments described above. For these experiments, the tip of the fiber was located at the nodal point of the eye in a model head ("Marty, the surgical simulator," Iatrotech, Inc.).

The experimental setup shown in Fig. 1 was again used except that this time the detector was a Gigahertz-Optik, Inc. optometer P9710. The model

head with the fiber was located on a specially designed holder and was oriented at a 30° angle with respect to the normal to provide a comfortable position for the clinician while directing the light at the end of the fiber in the model head.

The indirect ophthalmoscope used was a Propper Model A2035. The experiment was first conducted with a Volk 28D condensing lens and then repeated with a Nikon 20D lens. The appearance of the fiber, brightly illuminated by the focused beam, provided the visual feedback to the clinician and helped him to keep the light focused on the fiber tip. The clinician was also able to support his hand by placing his fingers on the forehead of the model as he would in a normal clinical examination.

The ratio of the relative radiant energy collected with the hand-held lenses or the head-mounted indirect ophthalmoscope or the combination of the two to the relative radiant energy collected with all components fixed was calculated. This ratio is a measure of how well the light from an indirect ophthalmoscope can be focused onto a 1-mm-diameter circular spot and thus indicates the extent to which the light can or cannot be stabilized in terms of movement relative to a single point.

In the first set of experiments with the slit lamp, like those conducted with the indirect ophthalmoscopes, one end of the fiber was connected to the UDT optometer. The other end of the fiber was located at a fixed position to represent the approximate location of the eye during an examination. The Volk Superfield NC lens was attached to the slit lamp's headrest at the approximate location where the light from the slit lamp was focused onto the end of the 1-mm-diameter fiber by an experienced clinician.

As in the experiments with the indirect ophthalmoscope, the UDT optometer was operated in the integrate mode to collect the radiant energy delivered to the detector from the fiber. Relative radiant energy data collected from the fiber illuminated by the slit lamp through the lens were recorded in a darkened room. An integration time of 45 s was also arbitrarily selected for these experiments.

As with the indirect ophthalmoscope experiments, the second set of experiments with the slit lamp was identical to the first set, except that the lens was held by the clinician instead of being fixed to the headrest of the slit lamp. The ratio of the relative radiant energy collected with the hand-held lens to that collected with the lens in a fixed position is a measure of how well the light from a slit lamp can be focused onto a 1-mm-diameter circular spot.

3. Results

The ratio of the mean values of relative radiant energy collected under various conditions with the hand-held condensing lenses and the head-mounted indirect ophthalmoscope, to the values collected when all the components were fixed and stationary, i.e., mounted on the optical bench, are listed in Table 1. The standard deviations, together with the maximum and minimum values obtained, are also listed in Table 1.

Table 1. Ratios of the Relative Radiant Energy Collected under Various Conditions with Hand-Held Lenses and the Head-Mounted Indirect Ophthalmoscope to the Relative Radiant Energy Collected with Fixed Components, along with the Standard Deviation and the Maximum and Minimum Values Obtained

Component and Mode of Use	Mean Ratio	Standard Deviation	Maximum Value	Minimum Value
Hand-held Topcon +14D lens	0.17	0.08	0.31	0.07
Hand-held Zeiss +20D lens	0.07	0.05	0.19	0.01
Hand-held Ocular +28D lens	0.27	0.18	0.54	0.03
Head-mounted indirect ophthalmoscope with fixed Zeiss +20D lens	0.25	0.20	0.61	0.00
Hand-held Volk 28D lens with head-mounted indirect ophthalmoscope	0.67	0.01	0.68	0.66
Hand-held Nikon 20D lens with head-mounted indirect ophthalmoscope	0.69	0.06	0.73	0.69

The mean of the ratios of the relative radiant energy collected with the hand-held lenses compared with those collected with fixed components ranged from 0.07 for the Zeiss +20D lens to 0.27 for the Ocular +28D lens. The standard deviations of the mean for the measurements with the hand-held lenses were large compared with the means and ranged from 0.05 for the Zeiss +20D lens to 0.18 for the Ocular +28D lens. Furthermore, the standard deviations of the means ranged from 47% of the mean for the Topcon +14D lens to 71% for the Zeiss +20D lens. The maximum ratios ranged from 0.19 for the Zeiss +20D lens to 0.54 for the Ocular +28D lens, whereas the minimum values of the ratios ranged from 0.01 for the Zeiss +20D lens to 0.07 for the Topcon 14D lens. The mean ratios for the observers using hand-held lenses varied from 0.07 to 0.38.

The mean of the ratios of the relative radiant energy collected with the head-mounted indirect ophthalmoscope to that collected with fixed components was 0.25, with a standard deviation of 0.20. The maximum value obtained with the head-mounted indirect ophthalmoscope was 0.61, whereas the minimum value obtained was 0.00. The mean ratios for the observers using the head-mounted indirect ophthalmoscope varied from 0.06 to 0.36.

In the combined case, with the head-mounted indirect ophthalmoscope and the hand-held lenses, the mean of the ratios of the integrated radiant exposures under the user-controlled conditions to those with the components in the fixed position was approximately 0.67 for the 28D lens and 0.69 for the 20D lens. The results with the experienced clinician were repeatable and varied from a low of 0.64 to a high of 0.73, both with the 20D lens. The maximum ratios obtained were 0.68 with the 28D lens and 0.73 with the 20D lens.

In the experiments with the slit lamp, the mean of the ratios of the relative radiant energy collected with the hand-held Volk Superfield NC lens to that collected with the lens in a fixed, clamped position was 1.04, with a standard deviation of 0.13. The maximum ratio obtained with the hand-held Volk lens was 1.18, whereas the minimum ratio obtained was 0.92.

4. Discussion and Conclusions

This work demonstrates that involuntary user movements can be significant, making it difficult not only

to keep the beam centered on a 1-mm circle but also to maintain the focus of the beam on a single point. In general the results were not observer dependent and, in the experiments in which either the lenses were hand held or the indirect ophthalmoscope was head mounted, the variability was large for each observer. For example, we were, on average, able to keep the beam focused on a 1-mm-diameter circle only 7%–27% of the time during a 45-s period when the lenses were either hand held or the indirect ophthalmoscope was head mounted. Furthermore, in the experiments in which either the lenses were hand held or the indirect ophthalmoscope was head mounted, the period that the beam could be maintained in focus varied considerably from 1% to 3% at one end of the scale to 50% to 60% at the other. The higher figure, however, indicates that there are occasions when involuntary movements do not have a significant effect. Indeed, this was confirmed by the experiments in which the hand-held condensing lens and the head-mounted indirect ophthalmoscope were used simultaneously. In this case it was possible to maintain the light focused onto the 1-mm-diameter spot for approximately 68% of the time. Based on the design and results of our experiments, we can reasonably conclude that the ability of users to deliberately focus the beam from an indirect ophthalmoscope onto a 1-mm-diameter circle on the cornea or lens is similar to that described in this work.

The results with the slit lamp are similar to those with the indirect ophthalmoscope and show that the light could be focused on a 1-mm-diameter circle almost 100% of the time during a 45-s period. Surprisingly, the maximum ratio of the radiant exposure with the hand-held lens to that obtained with the lens clamped in a fixed position was slightly greater than 1. We attribute this result to the slit-lamp's light not being critically focused onto the end of the fiber when the lens was fixed to the headrest of the slit lamp.

In setting limits and measurement conditions for safety standards, it is necessary to consider worst-case conditions. For both indirect ophthalmoscopes and slit lamps, we conclude that the data from this study of involuntary user movements do not provide sufficient evidence that the measurement conditions for evaluating the potential optical radiation hazards for the cornea and lens may be relaxed. It is hoped

that other studies will be carried out to more precisely define the measurement conditions for evaluating the potential optical radiation hazards to the eye from involuntary user movements associated with indirect ophthalmoscopes and slit lamps.

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